Submitted electronically

April 19, 2023

The Honorable Xavier Becerra
Secretary
US Department of Health & Human Services
Washington, DC 20201

On behalf of the Milken Institute, I write to share our insights and suggestions pertaining to the forthcoming expiration of the Public Health Emergency (PHE) for COVID-19 declared under Section 319 of the Public Health Service (PHS) Act. The Milken Institute is a nonprofit, nonpartisan think tank focused on accelerating measurable progress on the path to a meaningful life that we believe is built on a foundation of good physical and mental health. In order to achieve it, we must have systems that are innovative, patient-centric, and future-focused, and that acknowledge the vital relationship among the fields of medical research, public health, food systems, and healthy aging, the four areas of focus of Milken Health.

This letter provides our thoughts centered on three critical public health areas impacted by the PHE: data sharing and coordination, telehealth and technology-enabled home care, and equitable access to care and meeting social needs. The innovations and flexibilities implemented during the PHE led to improvements in the lives of individuals and communities nationwide. We believe harnessing these lessons learned, in permanent reforms, must be prioritized and accelerated for our nation's public health system to be strong and high-functioning at all levels.

Maintaining the PHE status has been essential to our nation's ongoing response to the COVID-19 pandemic for the past three years. The PHE declaration and its continuation have allowed the federal government the ongoing deployment of resources and authorities necessary to protect the public and assist states and localities in a number of critical ways which include:

- the coordination and collaboration across and amongst federal, state, and local agencies providing vital flexibilities for state, territorial and local health departments to reassign federally-funded personnel to assist with the response;
- the approval and availability of biomedical innovations at an expedited pace creating access to new diagnostic tools to further expand testing in both symptomatic and asymptomatic populations and novel medical countermeasures including vaccines and therapeutics;
- the implementation of measures to support local and state public health officials in performing their legally-mandated duties to keep the public healthy and safe, such as rapidly scaling the public health workforce;
- the deployment of strategies to protect communities that are historically under resourced with limited access to health care services.

COVID-19 laid bare widespread fragilities and inequities in *all* the systems impacting US health (health-care delivery, public health, and their ancillary systems). The pandemic also elucidated longstanding health and social inequities in the US, emphasizing that our ability to be prepared for the next public health emergency is dependent on addressing these disparities and their social and economic drivers. As we transition away from the emergency phase of the pandemic, our nation is at a critical inflection point where we must leverage numerous and important lessons learned to strengthen these systems and modernize their infrastructures to make them more resilient and sustainable. With the May 11, 2023, PHE expiration date drawing near, it is crucial every community and our nation as a whole have resources and partnerships in place to ensure the daily protection of public health needs of *all* Americans during steady state conditions and times of crisis.

Public Health Data Sharing and Coordination

We encourage HHS to revisit data sharing agreements and system upgrades necessary for accurate and equitable public health surveillance. Revisiting data sharing and infrastructure moves us toward more interoperable public health data systems that share health information appropriately, in the right format. We need sustainable systems that can receive timely, exchangeable data from various sources, like laboratories and hospitals, and exchange these data with HHS in an efficient manner. Now is the time for HHS to fund and operate pilot studies to understand real-world needs and potential use in different communities.

Outside of a public health emergency, the Centers for Disease Prevention and Control (CDC) has limited authority to collect public health surveillance data from state and local health agencies. With the unwinding of the PHE, reporting of COVID-19 lab results and immunization data to CDC will change given that HHS will no longer have authority to require lab test reporting for COVID-19. This may affect the reporting of negative test results and impact the ability to calculate percent positivity for COVID-19 tests in some jurisdictions, further complicated by the changes in overall test availability. CDC has been working to sign voluntary Data Use Agreements (DUAs), encouraging states and jurisdictions to continue sharing vaccine administration data beyond the PHE. Additionally, hospital data reporting will continue as required by the conditions of participation stipulated by the Centers for Medicare and Medicaid Services (CMS) through April 30, 2024; reporting, however, may be reduced from the current daily standard to a lesser frequency. Having to rely more on targeted passive surveillance systems and compiling data from a sample of healthcare facilities is suboptimal, which may lead to incomplete data sets that miss communities disproportionately affected by COVID-19.

We support data modernization initiatives that leverage cross-sector datasets to a broader range of interconnected public health partners solutions. Pre-COVID, cities received Supplemental Nutrition Assistance Program (SNAP) data annually. During the pandemic, SNAP data were shared with on-the-ground implementors more quickly and more frequently, enabling more effective implementation. Geographic-specific data were shared on a monthly basis for some jurisdictions, which allowed for targeted nutrition security responses in those areas. Looking beyond the pandemic, HHS and the USDA should form a partnership to create regular intervals of datasets (e.g., monthly or quarterly) so jurisdictions and communities can utilize them for real-time implementation. As CMS works to incorporate health-related social needs, like nutrition, in benefit programs, this cross-sector agency data coordination is crucial.

Telehealth and Technology-Enabled Home Care

Virtual care value streams emanating from the COVID-19 response substantiate the expansion and evolution of tech-enabled applications in a non-pandemic-driven health environment. The COVID-19 pandemic pushed US health systems to expand the use of telehealth and other digital health technologies to new heights. The previously sharp lines between brick-and-mortar health care and home care blurred, with an expanding body of evidence supporting new approaches that have emerged where care in the home is integrated with traditional health care in outside settings and exists on a spectrum considering patients' fluctuating needs over time.[i]

Though the Consolidated Appropriations Act (CAA) provided a patch through December 31, 2024, we support codifying longer-term telehealth flexibilities that are needed to provide quality, equitable care across geographic communities. Before the COVID-19 pandemic, Medicaid beneficiaries had the flexibility to use telehealth services in most states. Only traditional Medicare beneficiaries living in areas with a shortage of health-care professionals could access telehealth. Further, patients could not receive telehealth services in their homes and had to travel to specific "distant" or "originating site" such as a physician's office, hospital, or skilled nursing facility to utilize a telemedicine service. These geographic and originating site restrictions, along with distant site restrictions limiting the types of clinicians able to provide telehealth services, severely constrained the reach of virtual care for older adults. These restrictions were waived during the PHE, contributing to the rapid adoption of telehealth services among the older adult population. In addition, the availability of audio-only services during the pandemic supported equity in access to virtual care and filled gaps by addressing known barriers such as transportation and low-bandwidth, which proved vital for older adults and under-resourced communities, especially those in rural geographies.

We support long-term regulatory policies that retain the use of telehealth and remote monitoring tools in clinical research. In addition to enabling continuity of care for individuals when healthcare facilities were inaccessible, telehealth flexibilities enabled continuation and diversification of many non-COVID clinical trials. Furthermore, it substantiated a movement towards more decentralized trials and remote approaches to research that had been more than a decade in the making. Over the course of the pandemic, the US Food and Drug Administration (FDA) has issued a series of guidance documents that aimed at addressing disruptions to ongoing clinical trials and inability for patients to access much-needed therapies for patients. In a recent federal register notice, the agency indicated that while several COVID-19-related guidance documents will end with the sunset of the PHE, a subset of these guidance documents, including those that govern the use of telehealth and remote tools for clinical trials, will be extended for 180 days, and possibly, longer.[ii] Changes to FDA regulations to retain permanently the use of telehealth and remote monitoring tools in clinical research offer significant promise for accelerating clinical development, enabling more diversity in trials, advancing patient-centric approaches that were otherwise impossible in traditional clinical trials, and improving care access.[iii]

We praise recent HHS action to propose policies for making telehealth services for people with substance use disorder (SUD) permanent. Prior to the PHE, the Ryan Haight Act required at least one in-person medical exam before healthcare providers were able to prescribe controlled substances, like buprenorphine and methadone, used in SUD treatment. During the PHE, the Ryan Haight Act was suspended, expanding telehealth services and coverage for patients with SUD. There have been efforts to amend the Ryan Haight Act and encourage the US Drug Enforcement Administration (DEA) to activate the telemedicine special registration rule before PHE expiration. DEA and HHS issued a proposed rule

"Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation" on March 1, 2023. This rule represents a step in the right direction to create permanent change and seeks input from stakeholders, inclusive of those in SUD treatment and recipient communities.[iv] However, the proposed DEA and HHS rule change would still require at least one in-person visit for controlled substances. Additionally, patients who received telehealth-based prescriptions for any controlled substances during the PHE would be required to receive an in-person visit within 180 days of PHE expiration to continue their prescriptions. With existing mental health workforce shortages and barriers to pharmacies carrying treatment medicines, this could lead to hundreds of thousands of additional people without care or critically delayed care beginning in May 2023.

Over the last 6 months, Milken Institute Health conducted a landscape assessment, literature review, and interview series with 13 leaders across sectors to understand lessons learned, barriers to entry or success, and ways to embed evidence-based research and outcomes into digital health tools addressing SUD, offered by employers. **46% of the stakeholders interviewed** highlighted their concerns on the ending of the PHE and its impact on people experiencing a SUD. Throughout the research process, this concern emerged as an issue warranting attention through the regulatory process.

We applaud additional CAA requirements that call for the continued lifting of traditional Medicare geographic and originating site restrictions. Importantly, this includes the provision of coverage for audio-only telehealth services and extension of the Acute Hospital Care at Home (AHCaH) initiative where individual hospitals can seek waivers and Medicare reimburses for 'hospital at home' (HaH) services for two years post-PHE. HaH delivery care models have proven effective, with improved clinical outcomes and patient satisfaction, reduced costs, and safety comparable to inpatient care. For example, the HaH, an expansion of CMS' Hospitals Without Walls program, allows traditional Medicare beneficiaries to receive inpatient-level care at home, combining care delivered via telemedicine and home visits by nursing staff or other integrated health professionals. Additionally, the PHE enabled Medicare providers to deliver care across state lines to assist in pandemic relief efforts, including the provision of virtual care. While state licensing maintains primacy, federal actions can incentivize the interstate practice of telehealth at the state level and support reimbursement through Medicare (e.g., by authorizing Medicare to reimburse if the practitioner is allowed to practice across state lines).

While we are pleased that AHCaH is included in the bundle of two-year extensions in the Omnibus appropriations bill, it should be codified permanently. HHS must leverage this critical period effectively to gather data and best practices that will inform needed permanent solutions. Continued access to virtual care is particularly important for those with Alzheimer's disease and related dementias, given the unique nature of the care dyad and the need to support caregivers facing transportation and logistical challenges in accessing care for their loved ones.

We strongly encourage HHS to incorporate components of Food Is Medicine (FIM) interventions in codifying long-term telehealth flexibilities. FIM encapsulates a range of nutrition interventions intended to address the full spectrum of diet-related health needs, from prevention to treatment and management. Investing in these programs, particularly for those most at risk of experiencing food insecurity and diet-related diseases, can improve key day-to-day health indicators for patients, save the healthcare system billions in costs, and prevent millions of disease-related deaths. FIM interventions include everything from produce prescriptions to medically tailored groceries and meals, all nourishing food prescribed by a healthcare provider or health system. Patients "fill" prescriptions at eligible locations, such as partnering grocery stores or food delivery services, by purchasing eligible nutritious foods. Telehealth expansion and

reimbursement for FIM is critical to implementing these interventions. During telehealth appointments, patients may be screened for nutrition security or other diet-related risk to qualify for referral to FIM services. Additionally, telehealth dietary counseling from registered dieticians is a key component of many FIM interventions to ensure patients are coached towards sustained healthy eating habits.

We urge HHS to work with the USDA to extend technology-enabled care flexibilities to population-based nutrition security programs. This must include the SNAP and the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). During the pandemic, USDA had the authority to approve state-requested waivers for SNAP and WIC program flexibilities necessary to waive various in-person requirements for essential program functions, helping to alleviate the burdens on administrators, clients, and other stakeholders. Recent studies suggest the waivers facilitated ongoing WIC participation for families with young children in need of supplemental food and made "WIC safer, more accessible, and more convenient" for clients.[v] Over the first two years of the pandemic while waivers were in place, the program saw an 8.7% increase in participation among children, while overall participation increased in 21 states and the District of Columbia.[vi] These waivers will expire 90 days after the PHE ends. By providing supplemental foods, health-care referrals, nutrition education, and breastfeeding support for 6.4 million women, infants, and children, WIC is critical to ensuring access to healthy foods and health services. While the USDA has stated existing WIC regulations offer sufficient flexibility to obtain and provide medical documentation in a remote environment without waivers, HHS coordination and communication on explicit telehealth flexibilities and use is critical. Additionally, all waivers of the requirement that WIC transactions occur in the presence of a cashier will also end 90 days after the PHE ends. Online ordering and transactions proved to be a successful innovation that improved WIC and SNAP participation and overall nutrition security during the pandemic. Given that in an average month in 2019, WIC served only an estimated 57.4 percent of those eligible, these innovations and learnings should be extended past the emergency period to ensure the needs of a population especially vulnerable to food insecurity and health disparities are met.[vii]

Equitable Access to Care and Meeting Social Needs

HHS should further empower pharmacists to deliver health and wellness services after the PHE ends. Located within five miles of 90% of Americans, pharmacies serve as key community healthcare access points for the public. Pharmacists were granted additional powers through the Public Readiness and Emergency Preparedness Act (PREP), another emergency waiver linked to but not dependent upon the PHE. Under PREP authorities, HHS granted pharmacists and pharmacy technicians the ability to order and administer COVID-19 tests, vaccines, and therapeutics for patients as young as 3. Those authorities run through Oct. 1, 2024, but because pharmacists operate largely under state laws, the intersection of federal and state policies once the emergency expires in May is unclear. We support the passage of H.R. 7213, the Equitable Community Access to Pharmacist Services Act, first introduced in the House of Representatives on March 24, 2022, to expand Medicare coverage permanently to include services provided by a pharmacist including testing, drug regimens, and vaccines for COVID-19, influenza, and certain other illnesses.[viii] This bill also provides for coverage of pharmacist services during a public health emergency or to address health equity, which we also believe is essential.

We support federal coordination with states for Medicaid renewals to be prioritized and efforts to conduct outreach for enrollment assistance are taken to ensure individuals eligible for Medicaid remain covered. With the end of the Medicaid continuous enrollment provision on March 31, 2023, states will have to redetermine eligibility for everyone receiving Medicaid. As a result, many people will be at risk of losing Medicaid coverage, including those who are still eligible, due to paperwork and bureaucratic

challenges. Though the precise number of Medicaid enrollees who may be disenrolled during the PHE unwinding period is uncertain, it is estimated that millions of enrollees will lose coverage, mostly children and adults who are eligible due to ACA expansion.[ix] Furthermore, dual-eligible older adults need support to prevent loss of coverage under Medicaid which provides access to home-based services. This further exposes the need to evaluate why we have so many people on Medicaid in the first place and reimagine a system that truly provides quality care for individuals and communities historically excluded.

We recommend HHS consider permanent changes to Medicare requirements for coverage of a skilled nursing facility stay. Prior to the pandemic, traditional Medicare required a three-day prior hospitalization for coverage of a skilled nursing facility stay. This rule has been waived for the duration of the PHE, enabling qualifying older adults to receive needed rehabilitative care without an inpatient hospital stay, thereby reducing costs and preventing unnecessary transfers between care sites. It will be reinstated at the sunset of the PHE, except for specific programs, such as the Shared Savings Program. Given that this rule is often cited as a barrier to care, beneficial modifications to the rule should continue to be considered, such as counting observational stays toward the requirement.

CMS should support states in seeking federal approval for expanded services and identifying strategies to increase support for family caregivers, address the paid caregiver shortage, and decrease waiting lists for services. Pandemic-related flexibilities enabled modification of Medicaid Home and Community-Based Services (HCBS) programs in states, including the expansion of eligibility criteria, the increase in scope of covered services, and support of the home care workforce. At the end of the PHE, states will need to obtain federal approval through traditional avenues for expanded services (e.g., 1915(c) or 1115 waivers).

We believe other CMS pandemic flexibilities that address social needs should be made permanent. Medicare Advantage (MA) organizations were able to redesign benefit packages mid-year to address social needs. Meal delivery and other Food Is Medicine prescriptions were part of this redesign. Current Mid-Year Benefit Enhancements for MA plans are only allowed if they are provided in connection with the COVID-19 outbreak and may end with the end of the PHE. This would severely limit the ability of plans to respond to changing circumstances and meet the needs of their enrollees.

We encourage federal action to ensure individuals and families experiencing nutrition insecurity are supported adequately after the end of the PHE. The Biden administration expanded SNAP benefits in the spring of 2021 so that households already receiving the maximum amount, and those who received only a small monthly benefit, get a supplement of at least $95 a month. This extra assistance ended in March 2023, though several states stopped providing it earlier, reducing benefit levels by an average of $82 per month. Older adults will be among the most severely impacted with those at the minimum benefit level having their benefits **reduced** from $281 to $23 a month.[x] The end of the PHE will reinstate SNAP restrictions for higher-education students and able-bodied adults without dependents. Reverting to pre-pandemic benefits will reduce assistance at a time when nutritional security is at extreme risk with the high and rising costs of food.

We recommend focusing on efforts to reduce silos and increase collaboration between federal agencies to build more human-centered health and nutrition benefit processes. Medicare, Medicaid, and federal nutrition programs (SNAP, WIC, TANF) across multilevel jurisdictions must take a human-centered approach to eliminate redundancies and simplify the processes that individuals go through to access and maximize their benefits. To improve the individual's experience navigating multiple benefit programs simultaneously, it is essential for the government agencies overseeing these benefit programs to reduce

barriers in the enrollment and benefit redemption processes. This alignment must be designed to maximize eligible participant enrollment and engagement in benefits rather than constrain or diminish their dignity. The loss of Medicaid coverage will affect access to other food assistance programs, increasing nutrition insecurity. Known as direct certification, Medicaid coverage confers automatic income eligibility for free school meals and for WIC. As more than three-quarters of WIC participants rely on adjunctive eligibility, ending continuous coverage could result in a loss of WIC coverage.[xi]

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We welcome the opportunity to discuss any of these issues in greater detail at any time or convene conversations with our network of diverse stakeholders. We greatly appreciate your consideration of these insights and suggestions, and we look forward to working with you and your team.

Sincerely,

Esther Krofah, MPP
Executive Vice President of Health
Milken Institute

cc: The Honorable Bernie Sanders, Chair, US Senate HELP Committee
The Honorable Bill Cassidy, Ranking Member, US Senate HELP Committee
The Honorable Cathy McMorris Rodgers, Chair, US House Energy & Commerce Committee
The Honorable Frank Pallone, Ranking Member, US House Energy & Commerce Committee

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[i] Lauren Dunning and Caroline Servat, *Advancing Tech-Enabled Health and Home Care* (Milken Institute, April 2022), https://milkeninstitute.org/report/tech-enabled-health-home-care.

[ii] 15417. Department of Health and Human Services & Food and Drug Administration, *Guidance Documents Related to Coronavirus Disease 2019 (COVID–19)*, Federal Register. Vol. 88, no. 48: GPO, 2023, https://www.govinfo.gov/content/pkg/FR-2023-03-13/pdf/2023-05094.pdf (accessed March 21, 2023)

[iii] Kristin Schneeman and Alisha Sud, *Building Community-Based Infrastructure for Inclusive Research: Lessons from the Pandemic for Federal Action* (Milken Institute, May 2022), https://milkeninstitute.org/report/community-based-infrastructure-inclusive-research.

[iv] 12875. Department of Justice & Drug Enforcement Administration, *Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation*, Federal Register. Vol. 88, no. 40: GPO, 2023, https://www.govinfo.gov/content/pkg/FR-2023-03-01/pdf/2023-04248.pdf (accessed March 21, 2023)

[v] Alison K. Ventura, Catherine E. Martinez, and Shannon E. Whaley, "WIC Participants' Perceptions of COVID-19-Related Changes to WIC Recertification and Service Delivery," *J Community Health*, 47(2), (April 2022) : 184–192, https://doi.org/10.1007/s10900-021-01026-8; *Changes in USDA Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Operations During the COVID19 Pandemic: A First Look at the Impact of Federal Waivers* (U.S.

Department of Agriculture, December 2021), https://fns-prod.azureedge.us/sites/default/files/resource-files/FFCRA-WICWaiver-Prelim-1.pdf.

[vi] *WIC During COVID-19: Participation and Benefit Redemption Since the Onset of the Pandemic* (Food Research and Action Center, October 2022), https://frac.org/wp-content/uploads/wic-during-covid-19-2022.pdf.

[vii] "National and State Level Estimates of WIC Eligibility and Program Reach in 2019," United States Department of Agriculture, accessed March 21, 2023, https://www.fns.usda.gov/wic/national-state-level-estimates-eligibility-program-reach-2019.

[viii] "H.R.7213 - Equitable Community Access to Pharmacist Services Act," Congress, accessed March 21, 2023, https://www.congress.gov/bill/117th-congress/house-bill/7213/text?s=1&r=90.

[ix] Jennifer Tolbert and Meghana Ammula, "10 Things to Know About the Unwinding of the Medicaid Continuous Enrollment Provision," *Kaiser Family Foundation*, February 22, 2023, https://www.kff.org/medicaid/issue-brief/10-things-to-know-about-the-unwinding-of-the-medicaid-continuous-enrollment-provision/.

[x] "SNAP Emergency Allotments and Public Health Emergency: Preparing for the Hunger Cliff," Food Research and Action Center, accessed March 21, 2023, https://frac.org/programs/supplemental-nutrition-assistance-program-snap/emergency-allotments.

[xi] Allison Maria Lacko, Allison Bovell-Ammon and Richard Sheward, "Ensuring food security and health beyond the Covid-19 public health emergency," *STAT*, October 18, 2022, https://www.statnews.com/2022/10/18/ensuring-food-security-and-health-beyond-the-covid-19-public-health-emergency/.