AMERICAN ACADEMY OF FAMILY PHYSICIANS

February 14, 2023

Joseph R. Biden, Jr.
President of the United States
The White House
1600 Pennsylvania Avenue NW
Washington, DC 20500

Re: Ensuring Continuous Access to Care at the End of the COVID-19 Public Health Emergency

Dear President Biden:

On behalf of the American Academy of Family Physicians (AAFP), representing 127,600 family physicians and medical students across the country, I write to share recommendations for minimizing disruption and ensuring continuous access to comprehensive health care as the nation prepares for the end of the federal COVID-19 public health emergency (PHE) on May 11, 2023.

The AAFP appreciates the administration fulfilling its commitment to providing at least 60 days of notice before ending the PHE. As we noted in a previous letter to Secretary Becerra, the emergency waivers, flexibilities, coverage policies, and other actions provided family physicians and other frontline clinicians with urgently needed resources to care for patients and keep their practices open throughout the COVID-19 pandemic. Given that many of these policy changes have been in place for nearly three years and, in some cases, have significantly altered the health care coverage and delivery landscape, transitioning away from the federal PHE could cause considerable disruptions to physicians and their patients. **To ensure continuous access to comprehensive care after the end of the PHE, the AAFP again urges the administration to publish a comprehensive plan for unwinding the flexibilities and waiver authorities available under the PHE, as well as use its authority to minimize disruption.**

Below we offer specific administrative actions and considerations we recommend including in this plan and addressing before May 11, including:

- **Protect equitable, affordable access to COVID-19 vaccines, treatments, and testing;**
- **Ensure physician practices can purchase and stock COVID-19 vaccines once they transition to the commercial market, including by addressing inappropriate price inflation;**
- **Prevent Medicare telehealth coverage and payment disruptions;**
- **Protect patients' access to lifesaving opioid use disorder treatment via telehealth;**
- **Permanently allow Medicare payment for virtual supervision of residents and expand the Medicare primary care exception; and**
- **Remove administrative, cost, and other barriers for individuals with Long COVID seeking the health care services and federal assistance they need.**

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Protect Equitable, Affordable Access to COVID-19 Vaccines, Tests, and Treatments

The AAFP is pleased that most Medicare, Medicaid, Children's Health Insurance Program (CHIP), qualified health plan, and commercial beneficiaries and enrollees will be able to receive COVID-19 vaccines without patient cost-sharing once the PHE ends (provided that they are recommended by the Advisory Committee on Immunization Practices). Uninsured children will also be able to receive vaccines at no cost through the Vaccines for Children program. **However, the AAFP remains deeply concerned that uninsured adults will face significant barriers to obtaining affordable COVID-19 vaccines once they are transitioned to the commercial market.** We were strongly supportive of the Vaccines for Adults program that President Biden proposed in the Presidential budget. **We stand ready to work with Congress and the administration to enact and implement this program to ensure every patient, regardless of their insurance status, can receive recommended vaccines at no cost to them.**

We previously shared a slew of recommendations for ensuring continuous, affordable access to COVID-19 related care after the end of the PHE. The AAFP appreciates HHS clarifying in a recent fact sheet when and how certain coverage and payment policies for COVID-19 tests and treatments will change. We encourage HHS to continually share this information with clinicians and beneficiaries across programs and plan types. **We strongly recommend the administration use its rulemaking and oversight authorities to ensure all individuals have equitable, timely, and affordable access to COVID-19 treatments and testing services once the PHE and related coverage requirements conclude.**

The AAFP appreciated the administration developing and releasing plans for addressing Long COVID and accelerating related research. We commend the administration for centering the voices and experiences of patients with Long COVID in the development of these reports and encourage partnership with clinicians who are diagnosing and managing Long COVID. Family physicians and other primary care clinicians are playing a central role in diagnosing, managing, and treating Long COVID. **Additional administrative and legislative actions are urgently needed to ensure individuals with Long COVID have access to comprehensive health care, in addition to other federal, state, and local supports and services. We urge the administration to use its authority to remove administrative and cost barriers for individuals with Long COVID who continue to report significant challenges when seeking the health care services and federal assistance they need.**

Ensure Physician Practices Can Purchase COVID-19 Vaccines After Transition to Commercial Market

Family physicians and other health care professionals have faced significant financial hardships during the pandemic, in addition to worsening administrative burden. The federal government's commitment to purchasing and distributing COVID-19 vaccines and therapeutics during the PHE helped facilitate a more timely, equitable rollout.

The AAFP recognizes that COVID-19 vaccines will likely not be transitioned to the commercial market until several weeks or months after the PHE ends. However, **we are concerned that this transition will create financial and operational challenges for physician practices and could negatively impact access to and utilization of COVID-19 vaccines.** This transition will require primary care practices to begin purchasing the vaccines (multiple different vaccines for different age groups) and

file claims to be paid for vaccine and therapeutic products once they are administered to patients. If the price of the vaccines is too high, physician practices may struggle to make the upfront investment in COVID-19 vaccines and choose not to offer it in their practice. If various health insurers do not establish payment rates that accurately reflect the market price of the vaccine itself, as well as the unique costs of vaccine counseling and administration for COVID-19 vaccines, practices will face even greater challenges offering the vaccines. Evidence has demonstrated that patients prefer to receive vaccine counseling and administration from their usual source of primary care. As such, **the administration should work with Congress and use its available authority to ensure appropriate COVID-19 vaccine prices and payment rates to promote vaccine confidence and optimize vaccination rates.**

Specifically, the AAFP urges the administration to:

- **Provide *at least* 60-days of notice before the federal government will cease purchasing and distributing vaccines.**
- **Permanently cover and pay for vaccine counseling across programs and payers when it is provided separate from vaccine administration, including when counseling is provided via audio-only or audio/video telehealth.**
- **Modify the Medicare payment allowance for COVID-19 vaccine products as needed to ensure adequate payment for physician practices.**
- **Conduct monitoring and oversight activities to ensure states, Medicare Advantage organizations, and qualified health plans set adequate payment rates for COVID-19 vaccines and related services.**

Public Readiness and Emergency Preparedness (PREP) Act

During the PHE, HHS made many types of clinicians eligible to administer COVID-19 vaccines under the PREP Act by providing them with broad liability protections. We appreciate HHS clarifying in a recent fact sheet that these immunity protections are tied to government procurement of vaccines and other countermeasures and therefore will not change immediately when the PHE ends. **HHS should clarify in its comprehensive plan when PREP Act liability protections will end for clinicians, manufacturers, and program planners and provide a clear list of which clinicians are eligible to administer vaccines (and therapeutics, when relevant) once these protections end. While clarity is needed for stakeholders, the AAFP does not believe any other federal action to expand vaccine provider types is needed.** The COVID-19 pandemic has repeatedly illustrated patients' preference for receiving vaccines from their personal physician, followed by pharmacists and other vaccinators that are already able to administer vaccinations after the PHE ends.

Telehealth

The AAFP deeply appreciates HHS taking swift action to expand coverage and payment for telehealth services across programs during the COVID-19 PHE. The flexibilities implemented by HHS helped ensure timely access to care for patients while also helping to keep primary care practices open. Patients and clinicians agree that telehealth is a valuable modality of care that should be available and accessible after the end of the PHE. The AAFP is pleased Congress passed an extension of the current telehealth flexibilities, including coverage and payment for audio-only modalities, through December 31, 2024. **To prevent disruptions in Medicare coverage and payment for telehealth services, the AAFP recently joined several partners requesting CMS to promulgate an interim final rule modifying Medicare regulations to reflect the extension**

through 2024. Clarifying these regulations will provide family physicians and other clinicians with the certainty they need to continue offering telehealth services to Medicare beneficiaries.

The AAFP will continue to partner with Congress and the administration to develop permanent telehealth coverage and payment policies that ensure equitable access to high-quality telehealth while also protecting patient safety and care continuity. **As we noted in our previous letter, the AAFP recommends permanent telehealth policies:**

- **Provide all patients with timely, equitable access to telehealth services provided by and/or coordinated with their usual source of primary care;**
- **Refrain from directing or incentivizing patients to use direct-to-consumer telehealth services;**
- **Be designed to enable patients and physicians to select the most appropriate modality of care for each visit, including audio-only;**
- **Include programs, funding, and other provisions to improve equitable access to broadband and advance digital health literacy.**

HIPAA Waivers and Enforcement Discretion

During the PHE, HHS used its enforcement discretion to not issue penalties or violations of the HIPAA Privacy, Security, and Breach Notification Rules for using platforms to deliver telehealth services that are not HIPAA compliant. While this was an important and necessary decision that allowed physician practices to quickly adapt to COVID-19 safety protocols and integrate telehealth in their clinical workflows, the AAFP does not believe additional action should be taken to continue this enforcement discretion past the PHE. The HIPAA Security rule provides important protections to ensure patients' health care information and confidential conversations with their clinicians are kept confidential. Therefore, we believe HHS should resume enforcement after the end of the PHE. **The AAFP recommends HHS stipulate when it will resume enforcement in the comprehensive plan we have recommended and immediately issue notices to physician practices and other stakeholders alerting them about the resumption of enforcement.** This notice should share guidance released by HHS during the PHE to clarify how clinicians can use remote communication technologies in compliance with HIPAA rules.

The AAFP notes that the cost of purchasing, integrating, and maintaining HIPAA compliant telehealth platforms can be significant and could create barriers to implementation for small and independent practices. Connecting to HIPAA compliant platforms may also be more challenging for patients than using platforms that they are more familiar with (i.e., Facetime). **HHS should monitor the cost of telehealth platforms and access barriers that may cause disparate telehealth access for patients to determine if additional policy changes or federal funding are necessary.**

Prescribing of Controlled Substances and Substance Use Disorder Treatment

During the PHE, the Substance Abuse and Mental Health Services Administration (SAMHSA) in partnership with the Drug Enforcement Administration (DEA), waived in-person prescribing requirements and permitted remote prescribing of controlled substances using audio/video telemedicine without a prior in-person exam, regardless of the patient's location (if the prescribing is medically appropriate and the prescriber is DEA registered). These flexibilities have been particularly

vital for ensuring timely access to medication for opioid use disorder (MOUD) for individuals with opioid use disorder (OUD). **To preserve access to care and enable timely initiation of OUD treatment, the AAFP strongly urges HHS to work with the Department of Justice to make permanent flexibilities that allow physicians to prescribe OUD treatment via telehealth visits.**

In 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act (P.L. 115- 271) made changes to the Controlled Substance Act (CSA) requiring the DEA to promulgate a final rule specifying the circumstances in-which a special registration for telemedicine may be issued to enable safe remote prescribing of controlled substances and the procedure for obtaining the registration. **The AAFP continues to urge the DEA to promulgate a final rule for remote prescribing of controlled substances before the end of the PHE, as well as regulations facilitating access to OUD treatment via telehealth.** Failure to do so will disrupt access to MOUD for individuals with OUD. As SAMHSA noted in a recent proposed rule that would permanently enable opioid treatment programs (OTPs) to initiate buprenorphine treatment via telehealth, telehealth is an evidence-based method of providing MOUD that has been shown to improve treatment retention rates in many populations, including through the Veterans Health Administration's telemedicine MOUD program.[1, 2] Moreover, initial data from the CDC predicts a 14.9% increase in overdose deaths in 2021, indicating substance-use remains a growing and life-threatening problem in the U.S.[3] Making the telemedicine special registration process permanent as required by federal law is of utmost importance to addressing the overdose epidemic.

During the PHE, the DEA and SAMHSA also allowed practitioners to prescribe buprenorphine for the treatment of OUD to new or existing patients after a telephone consult. The AAFP applauded the DEA's action to make buprenorphine more accessible during the PHE by waiving in-person and video visit requirements. Given the rising mental health concerns and levels of overdoses during the pandemic, telephone consults have been a critical lifeline for ensuring access to buprenorphine and other forms of MOUD.[4] **The AAFP strongly encourages the administration to ensure the end of the PHE does not disrupt access to buprenorphine via telehealth. If the necessary DEA regulations are not finalized before the end of the PHE, DEA should continue to exercise its enforcement authority under the federal opioid crisis PHE.** Additionally, the AAFP strongly recommends HHS study the impact of audio-only prescribing of buprenorphine on patients' ability to access OUD treatment, as well as the impact on diversion and misuse.

Medicare Supervision Flexibilities

During the COVID-19 PHE, CMS adopted a policy on an interim basis allowing supervision of a resident by a teaching physician either in person or virtually through audio/video real-time communication technology during the key portion of the service. The goal was to ensure beneficiary access to necessary services and maintenance of sufficient workforce capacity to safely furnish services to patients. This policy generally requires real time observation by the teaching physician through audio video technology (not mere availability) and does not include audio-only (e.g., telephone without video). CMS recently finalized regulations to permanently allow Medicare payment for virtual supervision of residents by teaching physicians only when the patient and resident are located in a rural area. When telehealth services are provided by residents, virtual supervision by the teaching physician will only be allowed in rural areas.

The AAFP strongly encourages CMS to make supervision of residents in teaching settings through audio/video real-time communications technology permanent policy, regardless of the location of the patient or resident physician. The virtual presence promotes patient access, continuity, convenience, and choice; and it decreases the spread of communicable diseases. This does not preclude a teaching physician from providing a greater degree of involvement in services furnished with the resident. The teaching physician would still have the discretion to determine the appropriateness of a virtual presence rather than in-person depending on the services being furnished and the experience of the resident. The AAFP agrees with CMS that surgical, high risk, interventional, endoscopic, or other complex procedures under anesthesia should remain excluded. We further recommend HHS outline when and how supervision requirements will change once the PHE ends in the recommended comprehensive plan.

The Primary Care Exception

Under the "primary care exception," Medicare makes payment under the Physician Fee Schedule to teaching physicians in certain teaching hospital primary care centers for certain services of lower and mid-level complexity furnished by a resident without the presence of a teaching physician. Regulations require that the teaching physician must not direct the care of more than four residents at a time, must direct the care from such proximity as to constitute immediate availability, and must review with each resident (during or immediately after each visit) the beneficiary's medical history, physical examination, diagnosis, and record of tests and therapies. The teaching physician must have no other responsibilities at the time, assume management responsibility for the beneficiary seen by the resident, and ensure the services furnished are appropriate.

In response to PHE for COVID-19, CMS amended regulations to allow all levels of outpatient evaluation and management (E/M) visits to be furnished by the resident and billed by the teaching physician under the primary care exception. CMS further expanded the list of services included in the primary care exception during the PHE. Additionally, Medicare payment was allowed to the teaching physician for services furnished by residents via telehealth under the primary care exception if the services were on the list of Medicare telehealth services.

The AAFP is appreciative CMS expanded the list of services subject to the primary care exception to respond to the PHE for remote precepting of residents. This change provides educational training opportunities for applicable medical residents, expands patient access to primary care, and improves relational continuity of the patient and primary care physician in teaching centers. Expanding the primary care exception has benefitted beneficiaries and primary care training programs alike and we are concerned that returning to the previous policy will create disruption in primary care training programs, as well as unnecessary barriers to high-value primary care for beneficiaries. Thus, **the AAFP recommends HHS permanently expand the list of services subject to the primary care exception.**

Permanently expanding the primary care exception could help improve utilization of high-value recommended preventive care services, which is particularly important as many beneficiaries have yet to catch up on preventive care they may have forgone throughout the pandemic. Our members report that the absence of these high-value services on the primary exception list discourages their integration in residency training and day-to-day medical practice, negatively impacting physician training and beneficiary outcomes in the long term.

To better address the needs of beneficiaries, the AAFP strongly recommends HHS permanently expand the primary care exception to include:

- CPT codes 99201-99204 and 99212-99214
- G0402, G0438, G0439 – Welcome to Medicare and Annual Wellness Visits
- Telehealth CPT codes 99421-99423 both audio visual and audio only
- Transitional care management CPT code 99495
- G0444 - Annual depression screening, 15 minutes
- G0442 - Annual alcohol misuse screening, 15 minutes
- G0443 - Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes
- 99406 - Smoking and tobacco use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes
- 99407 - Smoking and tobacco use cessation counseling visit; intensive, greater than 10 minutes
- G0446 - Annual, face-to-face intensive behavioral therapy for cardiovascular disease, individual, 15 minutes
- G0447 - Face-to-face behavioral counseling for obesity, 15 minutes
- 99490 - Chronic Care Management services, first 20 minutes of clinical staff time directed by a physician or other qualified health care professional
- 99439 – Add-on code for CPT 99490 for each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional
- 99491 - Chronic Care Management services provided personally by a physician or other qualified health care professional, first 30 minutes
- 99437 – Add-on code for CPT 99491 for each additional 30 minutes provided personally by a physician or other qualified health care professional
- 99487 - Complex Chronic Care Management services; 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month
- 99489 - Add-on code for CPT 99487 that pays for each additional 30 minutes of Complex Chronic Care Management services per calendar month
- 99497 - Advance Care Planning including the explanation and discussion of advance directives; first 30 minutes, face-to-face
- 99498 - Add-on code for CPT 99497 (Advance Care Planning, each additional 30 minutes)
- 99341-99344 - Home visits, new patient
- 99347-99349 - Home visits, established patient

Continuous, Comprehensive Health Coverage

The AAFP applauds the administration for its efforts to create special enrollment periods and enact other policies to facilitate continuous, comprehensive, and affordable health coverage for all, particularly for the millions of Medicaid enrollees who are at-risk of losing their coverage beginning in April. **The AAFP strongly supports steps to prevent erroneous disenrollment and connect enrollees who lose coverage to other affordable, comprehensive coverage options. We urge the administration to use its oversight authority to ensure states are adhering to federal guidance and requirements throughout the Medicaid redeterminations process.** We also encourage agencies to partner with family physicians and other frontline clinicians to share timely information with patients to facilitate continuous health coverage.

Thank you for your consideration of these important and timely recommendations. The AAFP stands ready to the partner with the administration to ensure a smooth transition out of the federal COVID-19 PHE. Should you have any questions or wish to discuss our recommendations further, please contact Meredith Yinger, Manager of Regulatory Affairs, at (202) 235-5126 or myinger@aafp.org.

Sincerely,

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Board Chair, American Academy of Family Physicians

Cc: Dr. Ashish Jha, White House COVID-19 Response Coordinator
Xavier Becerra, Secretary, Department of Health and Human Services
Chiquita Brooks-LaSure, Administrator, Centers for Medicare & Medicaid Services
Dr. Robert Califf, Commissioner, Food and Drug Administration
Dawn O'Connell, Assistant Secretary for Preparedness and Response
Dr. Rochelle Walensky, Director, Centers for Disease Control and Prevention
Miriam E. Delphin-Rittmon, Assistant Secretary for Mental Health and Substance Use
Anne Milgram, Administrator, Drug Enforcement Administration

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