June 17, 2022

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Re: Considerations for Ensuring Timely Access to Care After the COVID-19 Public Health Emergency

Dear Secretary Becerra:

On behalf of the American Academy of Family Physicians (AAFP), representing more than 127,600 family physicians and medical students across the country, I write to share a number of recommendations HHS should consider before ending the COVID-19 public health emergency (PHE).

The AAFP appreciates the comprehensive actions taken by the Department and its agencies to respond to the COVID-19 pandemic over the last two years. 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 during these challenging times. Given that many of these policy changes have been in place for two 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 prevent disruption across the health care system, it is vital that HHS implements a transparent, intentional, and equity-focused approach to ending the PHE and unwinding its associated policy changes.**

The AAFP strongly recommends HHS publish a comprehensive plan outlining all the existing flexibilities and policies that will change once the federal PHE declaration expires. HHS should offer the public at least 60 days to comment on this plan and should work with other Departments, such as Treasury and Labor, to outline how it will minimize disruptions and address gaps in health care coverage and access. We strongly believe a comprehensive plan is needed to provide the public with ample notice ahead of a slew of policy changes. To ensure HHS has time to develop, publish, and respond to public comments on the plan, the AAFP recommends the federal PHE continue through at least the end of calendar year 2022.

Below we offer recommendations and considerations for how the Department should ensure continuous health care coverage and ongoing access to comprehensive care once the PHE ends. These recommendations are not meant to comprehensively address the future of every PHE waiver

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or flexibility, but rather highlight the areas where we believe action or additional information are most urgently needed. We urge HHS to supplement our recommendations with additional policy and programmatic considerations in its plan for transitioning out of the federal PHE.

Ensuring Availability of COVID-19 Vaccines, Testing, Treatment, and Public Health Guidance

Food and Drug Administration (FDA)

The FDA is tasked with ensuring the availability of safe and effective COVID-19 vaccines, therapeutics, and tests, as well as high-quality masks to prevent the spread of the virus. These products have been essential to protecting families and health care workers from contracting COVID-19, severe disease, and death. The AAFP has long supported the FDA's efforts to advance public health, and we've appreciated the agency's ongoing partnership throughout the COVID-19 pandemic.

Discussions around ending the PHE have created concern about how the FDA plans to address ongoing COVID concerns and focus on preventing and responding to future variants. The AAFP recognizes that emergency use authorizations (EUAs) of vaccines and therapeutics are not tied to the PHE. However, there is ongoing confusion and concern among health care professionals and other stakeholders that ending the PHE will reduce the availability of these products. The AAFP applauds the FDA for releasing guidance to testing manufacturers to ensure availability of tests after the end of the PHE and hopes to see this guidance and any related deadlines summarized in the comprehensive plan referenced at the beginning of this letter. We recommend the FDA commit to providing the public with at least 60 days of notice before the existing EUA designation expires.

The AAFP has ongoing concerns about our nation's ability to protect vulnerable populations, including immunocompromised individuals and unvaccinated young children, from new and existing COVID-19 variants. We appreciate FDA publishing a tentative timeline outlining its work to authorize vaccines for children under five as well as updated vaccines. However, we are concerned that ending the federal PHE will hamper FDA's ability to conduct accelerated reviews of vaccines for these children (or updated vaccines for people of all ages), as well as the distribution and accessibility of vaccines once they are authorized for this population. **The AAFP strongly recommends against ending the federal PHE until vaccines are authorized and easily available for children under five.**

We are similarly concerned with the shortage of therapeutics that are effective against new variants and believe ending the federal PHE could worsen the agency's ability to respond to new variants as they emerge. FDA should prioritize accelerated, robust review of products targeting new variants and continue to proactively share information with the public about its work to ensure vaccines, therapeutics, and tests are effective against new COVID-19 variants. The AAFP urges HHS to transparently explain how the end of the PHE may impact FDA's COVID-related workstreams and communicate a plan to minimize disruptions.

In summary, the AAFP urges HHS to:

- **Ensure the federal PHE continues until a safe and effective COVID-19 vaccine for all children under five years old has been authorized, distributed, and made widely available across the country.**

- **Clarify for the public how availability of COVID-19 vaccines, boosters, therapeutics, and tests will be impacted by the end of the PHE and outline any necessary steps HHS will take to minimize disruptions in the availability of these products.**
- **Provide at least 60-days of notice before the existing EUA designation expires.**
- **Accelerate and support the development and availability of monoclonal antibody and antiviral treatments that are effective against new COVID variants,**
- **Accelerate and support the development of updated COVID-19 vaccines to ensure individuals of all ages have access to effective vaccines as the pandemic progresses**
- **Continue to bolster our testing and surveillance capacity through the development of COVID-19 diagnostic tests, including at-home, rapid, and polymerase chain reaction (PCR) tests, and**
- **Continue working with the CDC to combat vaccine hesitancy and promote public trust in all recommended vaccines.**

Office of the Assistant Secretary for Preparedness and Response (ASPR)

ASPR has led the procurement and distribution of COVID-19 related medical countermeasures (vaccines and therapeutics), maintained the strategic national stockpile, and helped to address personal protective equipment and other supply shortages during the pandemic.

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 recommends ASPR continue to prioritize primary care practices in vaccine distribution, including for vaccines that may be authorized for children under five.

Discussions about the end of the PHE, coupled with disruptions in federal COVID-19 funding, have raised concerns about when and how the federal government will transition purchasing and distribution to "normal" operations. This transition will require primary care practices to begin purchasing the vaccines and file claims to be paid for vaccine and therapeutic products once they are administered to patients. This transition could disrupt access to vaccines and therapeutics, as well as create administrative and operational challenges for physician practices. To minimize these challenges, the AAFP urges HHS to provide at least 60-days of notice before the federal government will cease purchasing and distributing vaccines and/or therapeutics.

We note that one of ASPR's primary roles has been to determine how much of each vaccine and therapeutic should be delivered to each state based on available data. This methodology, though not always perfect, helped to facilitate equitable access during product shortages. Given the ongoing shortage of therapeutics that are effective against new variants, in addition to potential demand for new COVID-19 vaccines, the AAFP recommends ASPR continue to purchase and distribute vaccines and therapeutics for the foreseeable future. We believe this is essential for ensuring an equity-focused COVID-19 response.

During the PHE, HHS made many types of clinicians eligible to administer COVID-19 vaccines under the PREP Act. HHS should clarify in its comprehensive plan that the PREP Act will no longer be in effect once the federal PHE ends and provide a clear list of which clinicians are eligible to administer vaccines (and therapeutics, when relevant) after the end of the PHE. 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.

As the PHE comes to an end, the AAFP urges HHS to:

- **Continue prioritizing primary care practices in vaccine distribution.**
- **Clarify to stakeholders and the public when the federal government plans to stop purchasing and distributing COVID-19 vaccines and therapeutics, and provide at least 60-days' notice before transitioning to normal medical supply purchasing and distribution operations**
- **Publish a plan detailing coordination with medical distributors to ensure there is no disruption in the availability of COVID-19 vaccines and therapeutics**
- **Clarify that the PREP Act will no longer be in effect after the end of the PHE and provide a list of eligible vaccinators**
- **Continue to maintain the Strategic National Stockpile and establish coordination efforts to ensure primary care physicians have access to PPE and other essential supplies during future outbreaks or pandemics.**

Centers for Disease Control and Prevention (CDC)

The CDC leads COVID-19 federal data collection, reporting, and surveillance, the development of COVID-19 public health guidance, and plays an integral role in bolstering our nation's laboratory capacity to monitor and respond to COVID-19 caseloads. The AAFP has supported the CDC's evidence-based strategies to reduce transmission and ensure physicians have access to the data and resources they need to keep themselves, their team, their families, and their patients safe. Family physicians particularly rely on CDC's guidance, data analytics, surveillance, and vaccine safety monitoring programs to counsel their patients. These critical functions have been supported by data reporting requirements across the public health and health care sectors. The AAFP is concerned that many of these reporting requirements will sunset after the PHE ends and therefore CDC will no longer have robust data from labs, health departments, and hospitals to inform its surveillance or the development of public health guidance. We urge HHS to work with CDC and other agencies to expand reporting requirements so that CDC can continue to monitor the pandemic after the end of the PHE. The AAFP also encourages HHS to transparently share how the end of the PHE may impact CDC's surveillance efforts.

The CDC plays a vital role in bolstering vaccine confidence through the development of public health communications campaigns and partnerships with trusted stakeholders and community leaders. These are crucial efforts that must continue after the end of the PHE.

Finally, the AAFP urges HHS to ensure childhood COVID-19 vaccines and boosters are transferred seamlessly into the Vaccines for Children (VFC) program once the federal government stops purchasing and distributing them. The VFC program is essential for ensuring affordable access to ACIP-recommended vaccines for uninsured children and those covered under Medicaid and CHIP. Transitioning the childhood COVID-19 vaccines to the VFC program quickly and without disruption will help family physicians continue offering COVID-19 vaccines to children at no cost.

To this end, the AAFP recommends the HHS:

- **Provide labs, public health departments, and hospitals with ample notice regarding which data reporting responsibilities will remain after the PHE ends and clarify for the public how the end of the PHE will impact CDC's surveillance efforts.**
- **Work with CDC and other agencies to expand reporting requirements so that CDC can continue to monitor the pandemic and develop data-driven public health guidance after the end of the PHE**
- **Ensure physicians and other immunizers can stock COVID-19 vaccines and boosters through the Vaccines for Children program once the federal government stops purchasing and distributing vaccines.**
- **Continue to work with community and public health leaders to develop communications campaigns and partnerships to promote vaccine confidence.**
- **Clarify for the public that CDC will continue to monitor the safety of new and existing COVID-19 vaccines and boosters, and alert the public to any concerns, after the PHE ends.**

Coverage and Payment of COVID-19 Vaccines, Vaccine Counseling, Testing, and Treatment

During the PHE, coverage of vaccines, testing, and therapeutics without cost-sharing helped to ensure equitable access to the needed medical interventions to keep communities safe. Although there were significant gaps in vaccine, treatment, and testing rollout, requiring coverage of these services without cost-sharing ensured more timely and equitable access than would otherwise be expected given the well-documented effects of cost leading to delayed care. However, once the PHE ends, Medicare, Medicaid, and marketplace beneficiaries may be unable to access these lifesaving services due to coverage gaps and cost-sharing requirements. The AAFP urges CMS to take action to ensure timely, equitable access to COVID-19 vaccines, testing, and treatment across payers and programs. Across payers, CMS should take steps to ensure coverage and minimize cost sharing associated with COVID vaccines and therapeutics, including using CMS authority to place anti-virals in drug tiers with the most comprehensive coverage and minimal cost sharing.

Primary care physicians are regularly providing vaccine counseling because they are the public's most trusted source of vaccine-related information. When individuals are asked who they trust to provide reliable information about the COVID-19 vaccines, personal doctors, including family physicians, top the list, with 83 percent of adults saying they trust their own doctor a great deal or a fair amount and 85 percent of parents saying the same about their child's physician.[i] Many times, this vaccine counseling occurs independent of vaccine administration (e.g., because the patient subsequently refuses vaccination or elects to be vaccinated at a later date). Although CMS required state Medicaid agencies and Medicaid managed care plans to cover and pay for vaccine counseling for children up to age 21 when it is provided separately from vaccine administration, this requirement did not extend to Medicare, adult Medicaid beneficiaries, or private payers. T**he AAFP strongly urges HHS to require coverage of separate vaccine counseling for all ACIP-recommended vaccines across all programs and for all beneficiaries, including when counseling is provided via audio-only or audio/video telehealth.**

Medicare

HHS offered a number of flexibilities and changes to coverage under Medicare that were critical during the PHE. CMS finalized regulations requiring Medicare to permanently cover all EUA approved and fully licensed COVID-19 vaccines without cost-sharing, based on interpretation of section 3713(d) of the CARES Act. The AAFP is pleased that Medicare beneficiaries will continue to have coverage for all COVID-19 vaccines and recommended boosters under Part B once the PHE concludes.

However, we have some concerns about potential disruptions in the provision of those vaccines in family medicine practices when the federal government no longer purchases and distributes them for free and instead requires physician practices to buy the vaccines and submit Medicare claims for them. Prior surveys of family physicians have shown that many refer their patients elsewhere for adult vaccines with lack of adequate payment being the most common reason. This is especially true for small practices.

Thus, continued provision of COVID-19 vaccines and boosters to Medicare beneficiaries in the primary care setting as Medicare shifts to paying practices for the purchase of those vaccines depends heavily on setting the Medicare payment allowance at a level that covers practices' cost of acquiring and maintaining those vaccines. Where medical practices incur a cost for vaccines, the AAFP calls for adequate payment for the vaccine itself and all associated overhead costs (i.e., acquisition, storage, inventory, insurance, spoilage/wastage, etc.).

Due to ongoing uncertainty regarding when the federal government will stop purchasing vaccines, in addition to whether updated vaccines or additional boosters will be required to combat new variants, it is unclear what the price of COVID-19 vaccinations will be when physician practices begin purchasing them. The previously set payment allowance equal to 95 percent of the AWP may or may not be adequate. We urge HHS to modify the payment amount as needed to ensure physician practices are able to purchase and offer COVID-19 vaccines and boosters to their patients. We further recommend HHS give Medicare physician practices at least 60-days' notice of what Medicare intends to pay for COVID-19 vaccines and boosters, so those practices may make informed business decisions about whether they can afford to continue providing COVID-19 vaccines and boosters to their patients and, if so, have time to acquire the necessary supply of the vaccine at a cost covered by Medicare's planned payment rate. We further recommend that HHS direct its Medicare Administrative Contractors (MACs) and Medicare Advantage plans what to pay in this regard and communicate that clearly, consistently, and comprehensively to physician practices.

Additional action is needed to ensure Medicare beneficiaries' ongoing access to COVID-19 tests and treatments once the PHE ends. Current Medicare policies covering and paying for monoclonal antibody and antiviral treatments are contingent upon the PHE. Absent swift action and clear communication with clinicians and other stakeholders, the AAFP is concerned that coverage of and access to treatments and tests will be disrupted. We strongly recommend CMS publish guidance to MACs and Medicare Advantage plans stipulating when COVID-19 monoclonal antibodies, antivirals, at-home tests, and laboratory tests are covered for beneficiaries. These coverage policies should be designed to minimize barriers to care related to COVID-19 and reduce the spread of COVID-19 by providing beneficiaries with the treatments and tests they need to protect themselves. This guidance must be accompanied by educational information for clinicians and beneficiaries. To minimize disruptions, we strongly recommend CMS publish this information as soon as possible and no later than 60 days before the end of the PHE.

We recognize that Medicare Advantage plans are required to provide, at minimum, equal coverage to that offered by traditional (or fee-for-service) Medicare. The AAFP urges HHS to exercise its authority

to conduct the necessary oversight activities to verify that beneficiaries enrolled in Medicare Advantage plans have equitable, timely access to COVID-19 care. Based on findings from a recent HHS OIG report which indicate prior authorization and other utilization management processes create barriers to accessing care, the AAFP strongly urges CMS prohibit the use of prior authorization requirements for coverage of COVID-19 vaccines, tests, and treatments.

To preserve access to these services for Medicare beneficiaries, the AAFP strongly urges HHS to:

- **Notify beneficiaries, clinicians, and other stakeholders that Medicare will continue coverage of COVID-19 vaccines and boosters under Medicare Part B past the end of the PHE, without cost-sharing**
- **Permanently cover and pay for vaccine counseling when it is provided separate from vaccine administration, including when counseling is provided via audio-only or audio/video telehealth.**
- **Continue paying for COVID-19 vaccine administration using Medicare allowances established during the PHE until such time as the relative value of the COVID-19 and other vaccine administration codes can be thoroughly reviewed and revalued as appropriate**
- **Provide physicians, beneficiaries, and other stakeholders with at least 60 days of notice before transitioning the purchase of COVID-19 vaccine supplies to physician practices.**
- **Modify the Medicare payment allowance for COVID-19 vaccine products as needed to ensure adequate payment for physician practices.**
- **As soon as possible, but no later than 60 days before the end of the PHE, publish guidance to MACs and Medicare Advantage plans outlining when COVID-19 therapeutics and diagnostic services must be covered. Publish accompanying educational materials for beneficiaries and clinicians.**
- **Continue coverage of at-home COVID-19 tests for Medicare beneficiaries after the end of the PHE or, at a minimum, provide beneficiaries with 60 days of notice before coverage and/or cost of at-home tests will change.**
- **Ensure Medicare Advantage plans, at a minimum, follow the same policies recommended for traditional Medicare above.**
- **Prohibit the use of prior authorization and other utilization management techniques to determine coverage and payment for COVID-19 related services.**

Medicaid

HHS offered significant flexibilities to state Medicaid programs and provided guidance related to coverage of COVID vaccines, testing, and therapeutics. During the PHE, state Medicaid programs are required to cover testing, vaccines, and treatment for enrollees without cost sharing, and are required to continue covering these services one year after the PHE ends. States have also used federal funds through the American Rescue Plan Act to provide and administer vaccines.

CMS announced in late 2021 that state Medicaid agencies and managed care plans are now required to cover and pay for COVID-19 vaccine counseling visits for children and youth enrolled in Medicaid as part of the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit. As previously mentioned, the AAFP has advocated for vaccine counseling to be covered and paid for

across payers when it is provided separately from vaccine administration. We applauded this announcement and appreciate that CMS is requiring Medicaid coverage of this service for all recommended childhood vaccinations, including after the PHE. This new requirement will enable family physicians to provide time-intensive, patient-centered vaccine counseling and ultimately may help bolster vaccine confidence, as well as childhood vaccination rates. We were also pleased that, following AAFP advocacy, CMS recently released guidance to states on how to implement this new requirement.

The AAFP urges HHS to expand the requirement for states to cover and pay for separate vaccine counseling to adult Medicaid beneficiaries. To reduce barriers to vaccine counseling and improve equitable access, HHS should also encourage states to cover vaccine counseling when it is provided via audio-only or audio/video telehealth.

Finally, the AAFP recommends HHS use its authority to require or encourage states to cover without cost-sharing COVID-19 vaccines, therapeutics, and tests after the federal coverage requirements end. Coverage of adult vaccines, treatments, and diagnostic services typically vary by state and eligibility category. We are concerned that this could create barriers to lifesaving services and worsen health disparities. Specifically, HHS should use its monitoring and oversight authority to ensure states set adequate payment rates for COVID-19 related services. HHS should also consider incorporating specific network adequacy and other minimum access standards for COVID-19 related care in future rulemaking.

To preserve access to these services for Medicaid enrollees, the AAFP strongly urges HHS to:

- **Ensure states continue to provide coverage and payment for COVID vaccines, testing, and therapeutics for one year beyond the expiration of the PHE without cost-sharing, per federal requirements**
- **Require Medicaid and CHIP coverage and payment for separate vaccine counseling for all Medicaid beneficiaries.**
- **Encourage states to cover vaccine counseling when provided via audio-only and audio/video telehealth visits.**
- **Encourage states to cover COVID-19 vaccines, therapeutics, and diagnostic services without cost-sharing for all beneficiaries once federal coverage requirements expire**
- **Conduct monitoring and oversight activities to ensure states set adequate payment rates for COVID-19 related services.**
- **Consider implementing network adequacy and other minimum access standards for COVID-19 related care in future rulemaking.**

Private Payers

During the PHE, health plans on the group and individual markets are required to cover COVID-19 vaccines, tests, and testing-related services to enrollees without cost-sharing or prior authorization requirements, regardless of whether the services were provided by an in-network clinician or facility. Plans were also required to cover at least eight authorized at-home tests per enrolled individual per month.

Patients may incur cost-sharing for testing services, as well as vaccination and testing services provided by out-of-network clinicians after the end of the PHE. The AAFP urges HHS to use its

authority, in conjunction with the Departments of Labor and Treasury, to ensure consumers in the individual, small, and large group markets have robust coverage of COVID-19 vaccines, tests, and therapeutics without cost-sharing after the end of the PHE. HHS should continue to prohibit the use of prior authorization requirements to determine coverage for COVID-19 care and consider including specific network adequacy requirements for COVID-19 related care in future rulemaking. Finally, we urge HHS to require private plans to notify enrollees at least 30 days before the end of the PHE regarding any changes in coverage and cost-sharing for COVID-19 vaccines, tests, and therapeutics.

The AAFP urges HHS to:

- **Ensure enrollees, in the individual, small, and large group markets have robust coverage of COVID-19 vaccines, tests, and therapeutics without cost-sharing after the end of the PHE.**
- **Prohibit the use of prior authorization or other utilization management requirements to determine coverage for COVID-19 related care after the end of the PHE.**
- **Consider including specific network adequacy requirements for COVID-19 related services in future rulemaking.**
- **Notify enrollees at least 30 days before the end of the PHE regarding any changes in coverage and cost-sharing for COVID-19 vaccines, tests, and therapeutics.**

Access to and Payment for COVID-19 Vaccines, Tests, and Therapeutics for Uninsured and Underinsured Individuals

The AAFP has urged Congress to swiftly provide funding for the HRSA Uninsured and Coverage Assistance funds. Family medicine practices rely on these programs to pay for COVID-19 tests, therapeutics, and vaccinations provided to uninsured and underinsured individuals. The current lapse in funding for these programs impacts practices' ability to offer these services and could be worsening already disparate access to treatments, as well as prevent patients from getting the diagnostic services and vaccinations they need to protect themselves, their families, and their communities. We will continue to advocate for Congress to replenish the funds for this program and to ensure uninsured and underinsured individuals have access to these services after the end of the PHE.

Facilitating Continuous Affordable Coverage for All

Medicaid

Any states that received a temporary 6.2 percent increase in the federal medical assistance percentage (FMAP) for the duration of the public health emergency were barred from disenrolling beneficiaries during the PHE. Once the PHE ends, these continuous enrollment requirements will expire, and states will be required to conduct Medicaid eligibility redeterminations. We are deeply concerned that this process will cause significant disruptions in access to health care. Recent estimates indicate that millions of current Medicaid beneficiaries may lose coverage during the redetermination process. The AAFP applauded the recent guidance providing states with more time to complete eligibility redeterminations and outlining waivers and other strategies states can use to prevent disenrollment and facilitate continuous coverage once redeterminations begin. Minimizing coverage disruptions will improve care continuity and ensure patients can receive the care they need when they need it.

We have repeatedly recommended HHS provide states and Medicaid managed care plans with at least 120 days' notice before unwinding federal enrollment and maintenance of effort requirements.

We believe this advanced notice will assist states in deciding when to increase their workforce, ramp up enrollee outreach efforts, update their IT systems, and implement administrative processes needed to conduct redeterminations and minimize coverage disruptions.

The AAFP has provided several other recommendations for how HHS can support and encourage states to enhance outreach to current enrollees, prevent erroneous or unnecessary disenrollment, and help connect current beneficiaries to alternative coverage if their Medicaid renewal is denied. Below we list these recommendations, including supporting states to conduct ex parte renewals and integrating eligibility systems across eligibility groups and other safety net programs. The AAFP again urges HHS to provide states and other stakeholders with funding to leverage navigators and other enrollment assistance programs throughout the redeterminations process. We continue to believe these recommendations, as well as robust federal monitoring and oversight are essential for facilitating continuous coverage. We were pleased to see amended regulations governing redetermination are on the unified agenda at the Office of Management and Budget. The AAFP has urged HHS to promulgate these regulations to strengthen state requirements and beneficiary protections before the end of the PHE. We also noted that, in addition to finalizing new protections, aligning the end of the PHE with open enrollment periods would facilitate a coordinated outreach campaign to help Medicaid-eligible families protect their current coverage while smoothly transition those that lose coverage to marketplace plans.

During the PHE, 15 states opted to adopt a new optional Medicaid eligibility pathway, with 100% federal matching funds, to cover COVID-19 vaccinations, treatment, testing, and testing-related services for uninsured individuals. This eligibility pathway will expire at the end of the PHE, leaving these enrollees without affordable access to COVID-19 related services. HHS should direct these states to conduct outreach to these enrollees and provide them with additional information about how to enroll in comprehensive coverage through Medicaid or the marketplace. States should also be required to notify these enrollees at least 30 days before their coverage will end.

To minimize coverage disruptions for current Medicaid beneficiaries, the AAFP urges CMS to:

- **Provide states and Medicaid managed care plans with at least 120 days' notice before unwinding the FMAP and Maintenance of Effort (MOE) provisions of the Families First Coronavirus Response Act (FFCRA)**
- **Consider encouraging states to leverage navigators and/or provide states with funding for navigators to assist state health officials and Medicaid enrollees with the redetermination process,**
- **Require states to send reminder notices using at least two different modes of communication before terminating coverage,**
- **Develop fliers and signs to be distributed to physician offices, community health centers, hospitals, and other locations where enrollees may be regularly seeking care,**
- **Monitor enrollment indicators for groups that are particularly vulnerable and/or at risk of losing their coverage and ensure states are taking steps to make enrollment forms and other information accessible across languages and culturally competent**
- **Assist states with integrating their Medicaid eligibility systems for modified adjusted gross income (MAGI) and non-MAGI groups, Supplemental Nutrition Assistance Program (SNAP) and Temporary Assistance for Needy Families (TANF), as well as creating multi-benefit applications for SNAP, TANF, and childcare subsidies,**

- **Provide support, additional guidance, and technical assistance to states on ex parte renewals, particularly those that are conducting few or no ex parte renewals, to improve efficiency of the renewal process.**
- **Promulgate eligibility and redetermination regulations listed in the Unified Agenda to strengthen state requirements and beneficiary protections before the end of the PHE.**
- **Require states providing the optional Medicaid eligibility pathway to cover COVID-19 services to notify enrollees at least thirty days before their coverage ends and conduct outreach to connect these enrollees with comprehensive coverage.**

Medicare

The AAFP was pleased HHS recently issued a proposed rule streamlining Medicare eligibility and enrollment, including by addressing the burden of penalties on beneficiaries who miss their initial enrollment period. HHS also proposed to create several special enrollment periods, one of which would align with Medicaid coverage terminations. We believe, if finalized, these proposals would provide current Medicaid beneficiaries who missed their initial Medicare enrollment period during the PHE with much needed flexibility and relief from penalties and periods of uninsurance. However, given federal notice and comment requirements, it is unlikely this rule is finalized before late 2022. **To ensure that current Medicaid beneficiaries can enroll in Medicare and benefit from these protections once federal continuous enrollment requirements end, the AAFP strongly urges HHS to ensure these protections are finalized and effective before the end of the COVID-19 PHE.**

Considerations Regarding Other Flexibilities and COVID-19 Programs

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 for 151 days after the end of the PHE. As Congress and the administration develop permanent telehealth coverage and payment policies, we would like to share several recommendations to ensure equitable access to high-quality telehealth while also protecting patient safety and care continuity.

When provided as part of a patient's medical home, telehealth can enhance the patient physician relationship, remove barriers to care, and improve health outcomes. However, telehealth services provided by direct-to-consumer telehealth companies, which typically do not have access to patients' medical records and are not usually integrated with a patients' medical home, can result in care fragmentation. **The AAFP recommends HHS ensure that all patients have timely, equitable access to telehealth services from their usual source of care. We further recommend that permanent telehealth coverage and payment policies facilitate utilization of telehealth services provided by a patients' usual source of care and refrain from directing or incentivizing patients to use direct-to-consumer telehealth services.** For example, HHS should prohibit Medicare Advantage and marketplace plans from offering lower cost-sharing for DTC telehealth services. Network adequacy standards should also ensure patients across programs can access telehealth from their usual source of care, and states and plans should not be permitted to count

telehealth providers toward meeting network adequacy standards unless they also offer in-person care within the specific standard.

Relatedly, the AAFP would support the implementation of Medicare telehealth coverage guardrails, such as requiring an established patient relationship for some telehealth services. Medicare beneficiaries are often more complex and sometimes experience challenges using telehealth services. Ensuring beneficiaries receive telehealth services from a clinician that knows them and can access their health record will help ensure patients receive appropriate care, including in-person services when needed. A recent report from the HHS Office of the Inspector General found that 84 percent of Medicare fee-for-service telehealth visits are already being provided by clinicians who have an established relationship with the beneficiary. Other studies indicate patients prefer telehealth services provided by their usual source of care. Thus, implementing additional guardrails would help ensure high-quality services are being delivered to beneficiaries without unduly restricting access to care, while also safeguarding program integrity.

Permanent telehealth policies must include coverage of and proper payment for audio-only telehealth services across programs. The lack of modern broadband infrastructure has proven to be a primary barrier to equitable telehealth and digital health access for rural Americans, who are 10 times more likely to lack broadband access than their urban counterparts, leading to fewer audio/video visits. A report from the Assistant Secretary for Planning and Evaluation (ASPE) also found that Black, Latino, Asian, and elderly patients, as well as those without a high-school diploma, were more likely to rely on audio-only telehealth visits. The available data clearly indicate that coverage of and fair payment for audio-only services is essential to facilitating equitable access to care after the PHE-related telehealth flexibilities expire.

In addition to ensuring audio-only services are covered and paid for, permanent telehealth coverage and payment policies should be designed to enable patients and physicians to select the most appropriate modality of care for each visit. Physicians should be appropriately compensated for the level of work required for an encounter, regardless of the modality or location. The cognitive work does not differ between in-person and telemedicine visits. The AAFP believes payment should reflect the equal level of physician work across modalities while also accounting for the unique costs associated with integrating telehealth into physician practices. We recommend that CMS explore ways to establish payment for in-person and telehealth services that accounts for the differences in the practice's cost to provide the service. For example, in order to offer high-quality telehealth services, physician practices must purchase, install, and maintain HIPAA-compliant telehealth platforms and modify their clinical and administrative workflows. Many practices hire additional staff to help patients connect to and understand how to use telehealth platforms. Appropriately accounting for these unique costs will enable practices to regularly offer telehealth appointments and ultimately improve equitable, timely access to telehealth after the PHE.

Permanent telehealth policies must enable federally-qualified health centers and rural health centers to permanently provide telehealth services to the millions of low-income patients that rely on them for primary care. The AAFP is advocating for Congress to remove existing statutory restrictions on Medicare coverage and payment for telehealth provided by FQHCs and RHCs. HHS must also ensure Medicare and Medicaid policies support the full integration of telehealth into community health centers and provide patients with equitable access to these services.

HIPAA Waivers and Enforcement Discretion

The AAFP recommends HHS make permanent the HIPAA Privacy Rule waiver of the requirement to distribute a notice of privacy practices (45 CFR 164.20). The requirement to provide a notice of HIPAA protections at every patient encounter is unnecessary and administratively burdensome for both patients and physician practices. **The AAFP recommends HHS only require a notice be provided when either (1) the patient is new to the covered entity or (2) if the notice of privacy practices has changed since the patient's last encounter.** Additionally, covered entities should be required to make the notice available at a patient's request. We believe this approach will fulfill the intent of the original requirement while also minimizing unnecessary administrative tasks for clinicians and patients.

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 provide physician practices and other stakeholders with at least 60 days of notice before doing so.

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 assisted treatment (MAT) 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. We urge HHS to work closely with DEA to develop accompanying policies to facilitate access to OUD treatment once these regulations are finalized.** Failure to do so will disrupt access to MAT for individuals with OUD. Telehealth is an evidence-based method of providing MAT that has been shown to improve treatment retention rates in many populations, including through the Veterans Health Administration's telemedicine MAT program.[ii, iii] 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.[iv] 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 DATA-waived 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 MAT.[v] The AAFP strongly encourages HHS to work with DEA to detail the plan and timeline for transitioning prescribing practices after the end of the 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 PFS payment 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 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.

To continue to 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

HHS Provider Relief Fund

HHS' Provider Relief Fund (PRF), which is administered by the Health Resources and Services Administration (HRSA) has provided physician practices with emergency relief funding during the PHE. This funding helped many primary care practices keep their doors open during the pandemic and the AAFP is grateful for HRSA's efforts to assist practices amid extremely challenging circumstances.

Physician practices that received funds from the PRF were required to submit a report on the use of funds HRSA. Unfortunately, the reporting process has proven to be overly burdensome, particularly for small physician practices and those caring for rural and other underserved populations. AAFP members who have contacted us about the PRF reporting activity and its associated portal have uniformly expressed frustration with the experience and time involved. We previously shared a number of specific recommendations for how HRSA could streamline the reporting process and minimize the burden of reporting on physician practices. **The AAFP reiterates our recommendation for HRSA to reduce the burden of reporting on practices.**

The AAFP, along with several partners, recently wrote to HRSA expressing concern that some PRF recipient practices were unaware of the reporting requirements and are beginning to receive recoupment notices from HRSA. Following this letter, HRSA created a late reporting process to allow practices to request to submit a late report if they attest to experiencing hardship. The AAFP appreciates HRSA's responsiveness to our concerns but remain concerned that communications challenges coupled with the burdensome reporting process will continue to create challenges for practices to come into compliance with the existing requirements.

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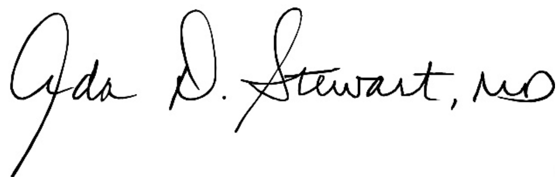
HHS provided many flexibilities in federal policy and program operations during the PHE for which we and our members are grateful. Particularly during the early stages of the PHE, those flexibilities were announced and implemented rapidly with ensuing clarifications and guidance following over time. With that in mind, we urge HHS and its agencies to minimize related audits and focus only on outliers while extending a corresponding amount of grace to the many front-line physician practices that have done their best to follow the fluid rules associated with those flexibilities during the most trying of circumstances.

The AAFP stands ready to partner with HHS to ensure a smooth transition out of the COVID-19 PHE. We again recommend the Department outline its transition plan and provide the public with as much

notice as possible before making policy and programmatic changes. This approach will enable organizations like ours to alert frontline clinicians and other stakeholders about forthcoming changes, which in turn will allow them to make the necessary clinical, administrative, or other operational modifications and minimize disruptions for patients. We welcome the opportunity to meet with you to discuss these recommendations. Should you have any questions or wish to schedule a meeting, please contact Meredith Yinger, Manager, Regulatory Affairs at myinger@aafp.org.

Sincerely,



Ada D. Stewart, MD, FAAFP
Board Chair, American Academy of Family Physicians

Cc: Department of Treasury
Department of Labor
Department of Justice

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