



December 16, 2020

Alex M. Azar II
Secretary, Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Steven Turner Mnuchin
Secretary, Department of the Treasury
1500 Pennsylvania Avenue NW
Washington, DC 20220

Eugene Scalia
Secretary, Department of Labor
200 Constitution Avenue NW
Washington, DC 20210

Re: RIN 0938-AU35; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency

Dear Secretary Azar, Secretary Mnuchin, and Secretary Scalia,

On behalf of the American Academy of Family Physicians (AAFP), representing more than 136,700 family physicians and medical students across the country, I appreciate the opportunity to provide comments on the Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency [interim final rule](#), as published in the November 6, 2020 version of the *Federal Register*.

Family physicians provide comprehensive primary care services for patients across the lifespan and are often patients' first contact with the health care system. Family physicians are serving on the frontlines of the COVID-19 pandemic and are simultaneously working around the clock to help patients catch up on delayed services and immunizations. They will play a vital role in counseling patients and reporting adverse events once a COVID-19 vaccine is approved. The AAFP appreciates the actions of the Department of Health and Human Services (HHS), the Department of the Treasury, and the Department of Labor to respond to the COVID-19 pandemic and resulting economic crisis. We are deeply concerned about the inequitable impact of COVID-19 and the significant financial strain that family medicine practices are facing. The AAFP looks forward to continuing to work with the Departments to respond to the pandemic and ensure access to affordable, high-quality primary care services now and in the future.

Medicare Coding and Payment for COVID-19 Vaccine

CMS clarifies its interpretation of and plans to implement section 3713 of the CARES Act, which established Medicare Part B coverage and payment for a COVID-19 vaccine and its administration.

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Regarding Medicare coverage, CMS notes the high-risk nature of the Medicare population, the circumstances of the current nationwide pandemic, and the FDA's guidance that an EUA may be appropriate for a COVID-19 vaccine before its licensure (if there is a demonstration of safety and efficacy in a clear and compelling manner from at least one Phase 3 clinical trial). Given those circumstances, CMS believes it is appropriate for Medicare to consider any EUA under section 564 of the FD&C Act issued for a COVID-19 vaccine during the PHE to be tantamount to a license under section 351 of the PHS Act for the sole purpose of considering such a vaccine to be described in section 1861(s)(10)(A) of the Act. That is, even though section 3713 of the CARES Act refers to a COVID-19 vaccine "licensed under section 351 of the PHS Act," CMS could consider any vaccine for which FDA issued an EUA during the PHE, when furnished consistent with terms of the EUA, to be eligible for Medicare coverage and payment.

Regarding coding and payment for COVID-19 vaccine and administration, CMS states that, because section 3713 of the CARES Act added the COVID-19 vaccine and its administration to section 1861(s)(10)(A) of the Act in the same subparagraph as the flu and pneumococcal vaccines and their administration, the Medicare allowed amount for the COVID-19 vaccine will also be 95 percent of the average wholesale price (AWP) (or reasonable cost, where applicable (e.g., under OPSP)). CMS anticipates establishing a unique administration code for each COVID-19 vaccine product and establishing specific coding and payment rates through technical direction to the MACs, including instructions to make this information available to the public. CMS also anticipates posting information on coding, payment, and billing for COVID-19 vaccines and vaccine administration on the CMS website. Lastly, CMS anticipates payment rates for the administration of other Part B preventive vaccines and related services, such as the flu and pneumococcal vaccines, would serve to inform the payment rates for administration of COVID-19 vaccines. CMS will allow COVID-19 vaccinations to be provided through the mass immunization and roster billing process that is in place for flu and pneumococcal vaccinations, and CMS is prepared to accommodate a two-dose initial COVID-19 vaccination schedule.

Of note, *in its Toolkit on Covid-19 Vaccine: Health Insurance Issuers and Medicare Advantage Plans*, CMS has said:

Medicare payment rates for COVID-19 vaccine administration will be \$28.39 to administer single-dose vaccines. For a COVID-19 vaccine requiring a series of 2 or more doses, the initial dose(s) administration payment rate will be \$16.94, and \$28.39 for the administration of the final dose in the series. These rates recognize the costs involved in administering the vaccine, including the additional resources involved with required public health reporting, conducting important outreach and patient education, and spending additional time with patients answering any questions they may have about the vaccine. These rates will also be geographically adjusted.¹

Finally, regarding Medicare Advantage (MA) and cost plans, CMS states all MA plans and cost plans must cover a COVID-19 vaccine and its administration described in section 1861(s)(10)(A) of the Act without patient cost sharing, as is the case under traditional Medicare. However, because the payment rates for MA organizations for contract years 2020 and 2021 have been set without including the costs for a COVID-19 vaccine and its administration, coverage of the new benefit will be provided through the Medicare FFS program until the MA capitation payments can take the new significant costs into account, consistent with federal law and regulations. The significant cost threshold will be met assuming that the projected cost per beneficiary-per-year is greater than approximately \$13. If

the threshold is reached, Medicare beneficiaries enrolled in MA plans will receive coverage of the COVID-19 vaccine and its administration through the Medicare FFS program and would be able to access the COVID-19 vaccine, without cost sharing, at any FFS provider or supplier that participates in Medicare and is eligible to bill under Part B for vaccine administration, including those enrolled in Medicare as a mass immunizer or a physician, non-physician practitioner, hospital, clinic, or group practice.

AAFP Response

The AAFP believes any vaccine for which the FDA issued an EUA during the PHE, when furnished consistent with terms of the EUA, should be eligible for Medicare coverage and payment. Like CMS, we believe this interpretation of section 3713(d) of the CARES Act is consistent with Congress' intent to provide for Medicare coverage without deductible or coinsurance of any COVID-19 vaccine (and its administration) that FDA has authorized, which would be the case both for a vaccine that receives EUA or full licensure. AAFP policy states that all insurers should cover immunizations recommended by the Academy without copayments or deductibles.²

Although the CARES Act does not tie Medicare vaccine coverage to the recommendations of any independent advisory panels, the AAFP is strongly supportive of the Advisory Committee on Immunization Practices (ACIP) and we believe that recommendations made by ACIP and other independent panels should play a role in the vaccine distribution and administration process. Independent panel recommendations can also help combat vaccine hesitancy and alleviate concerns related to political interference in the vaccine development process.

We believe setting the Medicare payment allowance for the vaccine itself equal to 95 percent of the AWP (or reasonable cost, where applicable) is reasonable in the long run, given section 3713 of the CARES Act added the COVID-19 vaccine and its administration to section 1861(s)(10)(A) of the Act in the same subparagraph as the flu and pneumococcal vaccines and their administration, which are also paid at 95% of the AWP. In the short term, we understand the vaccine will be purchased by the federal government and given to physician practices and other immunizers for free, which we support. Until market forces have settled the AWP, we believe it is imperative for Medicare to either provide the vaccine for free to physicians and other immunizers or otherwise pay physicians' actual cost for the vaccine. The PHE has placed many family medicine practices on precarious financial footing, such that family physicians cannot afford to lose money on the COVID-19 vaccines they administer. Many family physicians cannot access vaccines at a wholesale price, let alone 95% of the average wholesale price. They must be financially protected during the initial rollout of any COVID-19 vaccine.

We conditionally support setting the Medicare payment allowance for COVID-19 vaccine administration at a level comparable to that of administration of other Medicare Part B-covered vaccines. We believe this approach is reasonable, given section 3713 of the CARES Act added the COVID-19 vaccine and its administration to section 1861(s)(10)(A) of the Act in the same subparagraph as the flu and pneumococcal vaccines and their administration. There are two conditions for our support.

First, CMS must value HCPCS codes G0008, G0009, and G0010 appropriately and at a level that will support beneficiary access to vaccinations, which is vital to public health. In the 2021 Medicare Physician Fee Schedule (MPFS) final rule, CMS chose to maintain the payment rate for these services at the 2019 level. CMS did so even though the 2019 level is based on a crosswalk to CPT

code 96372 (*Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular*), a crosswalk CMS proposed to abandon in the 2021 MPFS proposed rule and which results in payment rates substantially lower than current Centers for Disease Control and Prevention regional maximum charges. Further, the 2019 rates reflect two years of reduced payment from the 2017 rates Medicare paid before the revaluation of CPT code 96372 led to the current undervaluation of immunization administration. The 2019 rates, which are now the 2021 rates, for G0008, G0009, and G0010 are not appropriate for setting the Medicare payment allowance for COVID-19 vaccine administration. The AAFP is very concerned that these inadequate payment rates will undermine access to essential vaccinations, including the COVID-19 vaccine. **We recommend that CMS use existing emergency authority under the PHE to immediately increase the values of HCPCS codes G0008, G0009, and G0010.**

Second, **CMS must value the CPT codes for COVID-19 vaccine administration in such a way that the relative value reflects the additional practice expenses associated with administration of the corresponding COVID-19 vaccines.** This recommendation is consistent with AAFP policy, which calls for adequate payment for the vaccine itself and all associated overhead costs.³ For instance, some of the vaccines being developed will require ultra-cold storage, defrosting, and be generally more expensive to store and administer. Our reading of the interim final rule suggests CMS will pay the same amount for administration only dependent on doses required, not based on the type of vaccine. Establishing a unique administration code for each COVID-19 vaccine product and a payment rate specific to each administration code will facilitate appropriate payment in this regard, even though it complicates the billing process by requiring physicians to choose from among multiple COVID-19 vaccine administration codes. Further, we anticipate that the time and resources required of clinicians who are administering the COVID-19 vaccine will be significantly greater than for flu and other vaccines. Family physicians and other clinicians administering the vaccine will have to spend time and practice resources to counsel patients on the safety and efficacy of a new COVID-19 vaccine, discuss the V-safe program and encourage patients to participate, as well as fulfill reporting requirements. It is likely that current Medicare rates for vaccine administration will not sufficiently account for the resources required to stock, store, and administer a new COVID-19 vaccine. We strongly recommend that the value of the unique CPT codes for COVID-19 vaccine administration reflect these additional costs.

We appreciate that CMS has plans to ensure that Medicare beneficiaries enrolled in Medicare Advantage and cost plans will be able to receive administration of a COVID-19 vaccine without cost sharing, as is the case under traditional Medicare. We agree that the cost of the vaccine and administration will likely exceed estimated significant cost threshold, which means these beneficiaries will receive coverage of the COVID-19 vaccine and its administration through the Medicare FFS program. Given that expectation, we have the following question and concern we want CMS to address before implementing this provision:

To whom will physicians need to submit their claims for these services: the beneficiary's Medicare Advantage plan or the MAC that otherwise processes Medicare FFS claims? We believe most physician offices are set up to submit claims to the patient's Medicare Advantage plan when an MA patient presents for a service. We believe physician offices should submit claims for the COVID-19 vaccine and its administration to the patient's Medicare Advantage plan, too, and be paid accordingly. If the anticipated coverage under Medicare FFS means those claims must be sent to the MAC, then we believe the onus should fall upon the MA plans to transfer the claims and receive reimbursement

from the MAC for those claims paid, rather than requiring physician offices to create an exception to their systems or wait longer for payment while claims are transferred from the MA plan to the MAC.

We believe MA plans have the necessary reserves, resources, and ability to manage such a transfer and that it will, thus, be less of a burden to them than it would be to physicians' offices. Physicians' offices, particularly primary care physicians' offices, are struggling to stay afloat financially during the ongoing pandemic. Medicare Advantage plans, whose parent companies do not face the same struggles. To the extent there are any changes in claims processing required as a result of covering COVID-19 vaccines and their administration for Medicare Advantage beneficiaries under Medicare FFS, the burden should fall entirely upon MA plans, and CMS should protect the physicians immunizing MA beneficiaries.

COVID-19 Vaccine Coverage for Medicaid, CHIP, and BHP Beneficiaries

CMS indicates that the Families First Coronavirus Response Act (FFCRA) requires that states and territories receiving a temporary 6.2 percent increase in the federal medical assistance percentage (FMAP) for the duration of the public health emergency are required to cover a COVID-19 vaccine and vaccine administration without cost sharing through the quarter during which the PHE ends. States are also required to pay physicians and other clinicians an administration fee or reimburse for an office visit even if the vaccine product is provided at no cost.

CMS also indicates that the agency does not interpret FFCRA section 6008(b)(4) to require states to provide COVID-19 testing and treatment services without cost-sharing, including vaccines and their administration, to eligibility groups whose coverage is limited by statute or under an existing section 1115 demonstration to a narrow range of benefits that would not ordinarily include this coverage, such as groups that receive Medicaid coverage only for COVID-19 testing, family planning services and supplies, or tuberculosis-related services. Instead, these groups would be considered "uninsured" for the purposes of receiving a COVID-19 vaccine, and clinicians would be reimbursed for the administration of a vaccine to these populations through the Provider Relief Fund.

After the end of the PHE, states will be required to cover COVID-19 vaccines recommended by the ACIP and their administration for several populations. For other populations, the state can elect to cover a COVID-19 vaccine but is not required to cover the vaccine or its administration. Except for the pregnancy-related coverage group, if a state elects to cover a COVID-19 vaccine for these groups, they must cover it for the other eligibility groups as well. The state also has the option to apply cost sharing for a COVID-19 vaccine and its administration, unless the beneficiary is covered under an eligibility group that is exempt from cost sharing.

CMS indicates that they do not believe the requirement to cover a COVID-19 vaccine and its administration without cost sharing applies to separate CHIP programs or Basic Health Plan programs.

AAFP Comments

The AAFP agrees with the agency's interpretation of FFCRA to mean that states accepting the increased FMAP must cover COVID-19 vaccine administration without cost sharing during the PHE and through the end of the quarter in which the PHE ends. We have heard from our partners that some state policymakers do not believe this coverage requirement applies to a vaccine that receives

EUA instead of full licensure. It is our understanding that states are required to cover the cost of vaccine administration regardless of the type of approval it receives from the FDA. The AAFP recommends that CMS issue clarifying guidance to states to ensure that all eligible Medicaid enrollees have access to the forthcoming COVID-19 vaccine at no cost to them through the end of the quarter in which the PHE ends, whether the vaccine receives an EUA or full licensure.

We also agree that states are required to compensate providers for vaccine administration. However, the AAFP is concerned that Medicaid reimbursement rates for both vaccine administration and office visits are insufficient, particularly for administering a new COVID-19 vaccine. CMS acknowledges that COVID-19 vaccine administration will require additional counseling, documentation, and other physician work than would be required for a typical immunization. Further, some of the vaccines that are in late-stage trials or are currently being considered by the FDA require ultra-cold storage. Taken together, all of this additional physician work will be time and resource intensive for family medicine practices and other vaccine providers. To ensure timely and equitable access to the vaccine for Medicaid enrollees, it is vital that state Medicaid agencies adequately reimburse for these costs. We recognize that states have broad authority to set vaccination payment rates and we appreciate the agency urging states to ensure that their payment rates are sufficient. The AAFP recommends that CMS encourage state Medicaid agencies to adopt payment rates that are at least equal to Medicare payment rates for COVID-19 vaccine administration.

The AAFP does not agree with the interpretation of FFCRA section 6008(b)(4) to not require states to provide COVID-19 vaccine coverage without cost sharing for beneficiaries within eligibility groups whose coverage is limited by statute or under an existing section 1115 demonstration to a narrow range of benefits that would not ordinarily include this coverage. Congress clearly intended *all* Medicaid enrollees, including those covered by a section 1115 demonstration, receive coverage for COVID-19 testing, treatment, and vaccinations. In fact, this section of the FFCRA explicitly indicates that states will lose the FMAP increase if they do not provide coverage for these services under a waiver demonstration:

“(b) Requirement for All States.-- A State described in subsection (a) may not receive the increase described in such subsection in the Federal medical assistance percentage for such State, with respect to a quarter, if...

(4) the State does not provide coverage under such plan (or waiver), without the imposition of cost sharing, during such quarter for any testing services and treatments for COVID-19, including vaccines, specialized equipment, and therapies.”⁴

As such, the Academy strongly recommends that CMS issue a final rule correcting this interpretation and **providing that states must cover COVID-19 testing, therapeutics, and vaccination without cost sharing for all Medicaid enrollees during the PHE, regardless of their benefit category and including those covered under an existing 1115 demonstration.** None of these enrollees should be considered uninsured for the purposes of vaccine coverage and reimbursement.

The AAFP is also concerned that the COVID-19 Claims Reimbursement Program is administratively burdensome and does not reimburse for services provided to uninsured individuals in a timely manner. One analysis found that the eligibility criteria for the Claims Reimbursement Program were stringent and created administrative challenges for physicians and hospitals that were seeking reimbursement.⁵ For instance, HHS required that patients not have any health insurance and had a

primary diagnosis of COVID-19. It is also unclear whether there will be ample funds allocated to this program in order to support widespread vaccination of uninsured individuals, since the pool of eligible patients would be much larger than in previous months and Congress has not authorized additional funding. Given the high cost of vaccination storage and administration, we do not believe that the Claims Reimbursement Program will ensure that uninsured individuals have timely and equitable access to a vaccine.

Price Transparency for COVID-19 Diagnostic Tests

The CARES Act requires group health plans and issuers providing coverage for items and services described in section 6001(a) of the FFCRA to pay any provider of a COVID-19 diagnostic test an amount that equals the negotiated rate, or, if the plan or issuer does not have a negotiated rate with the provider the cash price for such services that is listed by the provider on a public website. Section 3202(b) of the CARES act establishes a requirement for each provider of a diagnostic test for COVID-19 to publicize cash prices for such COVID-19 diagnostic testing. The provider of the test must make the cash price available on a public internet website during the emergency period declared under section 319 of the PHS Act. The Secretary may impose a civil monetary penalty on any provider of a diagnostic test for COVID-19 that does not make public its cash price for the test. CMS is adopting a new 45 CFR part 182 “Price Transparency for COVID-19 Diagnostic Tests” that will implement the price transparency requirements. For the purposes of section 6001(a)(1) of the FFCRA, COVID-19 diagnostic tests include all *in vitro* diagnostic tests, which include molecular, antigen, and serological tests. CMS seeks comments on this definition.

CMS defines “provider of a diagnostic test for COVID-19” as any facility that performs one or more COVID-19 diagnostic tests. CMS expects any provider of a COVID-19 diagnostic test would either hold or have submitted a Clinical Laboratory Improvement Amendments (CLIA) application necessary to obtain a CLIA certificate (including a certificate of waiver, as applicable) and that such testing would occur in facilities ranging from primary care provider offices to urgent care centers to stand-alone national laboratories.

CMS is defining “cash price” as the charge that applies to an individual who pays in cash. CMS expects the “cash price” will be generally similar to, or lower than, rates negotiated with in-network plans and insurers. If a provider has not established a price that is lower than its gross charge or retail rate, the provider must make public the undiscounted gross or retail rate found in its master price list. CMS does not believe posting the “cash price” should prevent a provider of a diagnostic test for COVID-19 from offering testing for free to individuals as charity care or to combat the public health crisis.

These requirements are applicable during the COVID-19 PHE.

The provider of the COVID-19 diagnostic test must make the “cash price” available on their website and the information itself or a link to a webpage that contains such information must appear in a conspicuous location on a searchable homepage of the provider’s website. If the provider does not have a website, they must make public its cash price information in writing upon request within two business days and by posting signage prominently at the location where the provider offers the test. If the provider does not have a website or publicly accessible location, then they must provide the information to the requestor in writing within two business days. Email is an acceptable written format.

CMS seeks comment on these issues, including the frequency by which providers may not have websites.

CMS seeks comment on whether consumers would benefit from knowing the total cost of care for receiving a COVID-19 test, including the doctor's visit and specimen collection. Specifically CMS seeks comment on whether a "provider of a COVID-19 diagnostic test" should be expanded to include providers that perform additional services related to the performance of the diagnostic test, such as for specimen collection or mileage fees that may be billed as part of or in conjunction with the specimen collection. CMS is interested in submissions from stakeholders that include data, both anecdotal and claims-based, on the ways in which consumers request and receive COVID-19 diagnostic testing, including site of care, frequency, and type of provider.

CMS anticipates relying predominantly on complaints made to CMS by the public. The monitoring methods for compliance with the requirement to post cash prices for COVID-19 diagnostic tests may include, but are not limited to:

- CMS' evaluation of complaints made to CMS;
- CMS' review of an individual's or entity's analysis of noncompliance as stated in the complaint;
- CMS' review of providers' websites or its written notice and signage.

If a provider is deemed noncompliant, CMS may:

- Provide a written warning notice to the provider of the specific violation(s);
- Request that a provider submit and comply with a corrective action plan (CAP);
- Impose a civil monetary penalty (CMP) if the provider fails to respond to CMS' request to submit a CAP or to comply with the requirements of a CAP approved by CMS.

A provider that receives a warning letter may choose to submit documentation to review to determine compliance. CMS will review the documentation submitted to determine if the provider's noncompliance has been corrected.

CMS seeks comments on this approach for monitoring providers of a COVID-19 diagnostic testing for compliance with these requirements. Specifically, CMS seeks comments on relying predominantly on complaints to determine a provider's potential noncompliance. CMS seeks comment on issuing warning letters and requesting CAPs for violations to the requirement to post cash pricing for COVID-19 diagnostic testing. CMS seeks comment on the time they should specify in warning notices to allow corrections of violations before issuance of a request for a CAP, and the time they should specify for providers to complete and submit a CAP to CMS.

CMS may impose a CMP on provider identified as noncompliant with any of the requirements of §182.70(a) and that fails to respond to CMS' request to submit a CAP or comply with the requirements of a CAP. Under statute, the maximum daily dollar amount for a CMP is \$300, even if the provider is in multiple discrete violations of §182.40. A provider must pay the CMP in full within 60 calendar days after the date of the notice of imposition of a CMP from CMS. If the provider has requested a hearing, the provider must pay the CMP in full within 60 calendar days after the date of a final and binding decision to uphold the CMP.

CMS seeks comment on the approach they are establishing for imposing a CMP on a provider noncompliant with the regulations at §182.40. CMS seeks comment on the time allowed between the

issuance of the request for a CAP and the imposition of a CMP. CMS seeks comment on the amount of the CMP imposed per day.

AAFP Response

The AAFP notes that a serological test is not a diagnostic test and should not be included in the definition of a COVID-19 diagnostic test for the purposes of this requirement. Therefore, providers of antibody testing should not be required to post the cash price of such a test on their website.

The AAFP understands the importance of price transparency, particularly during the PHE when many patients may have lost their health insurance or may be struggling financially. To mitigate concerns of price gouging by out-of-network providers, the AAFP believes the “cash price” should be no higher than the Medicare rate for a particular COVID-19 diagnostic test. Additionally, requiring a provider to post the cash price for the total visit would be extremely burdensome. Each patient and visit will be different, making it nearly impossible for a practice to be able to estimate the potential total cost of the diagnostic COVID-19 test and visit.

To alleviate the burden associated with complying with this requirement, the AAFP believes providers of a COVID-19 diagnostic test should have the flexibility to display the information in a way that is most appropriate for their patient population, including flexibility to decide between “cost” and “price” and “COVID” and “coronavirus.” CMS should also provide template language that practices could use on their websites. The AAFP disagrees with CMS’ decision to make public cash pay pricing information in writing upon request within two business days. Prior to the pandemic, physician practices were already overwhelmed with administrative burden. Asking physicians to respond in writing within two business days, coupled with administrative and the burdens of the PHE, is too much to ask of physicians. Many practices may instead choose not to offer COVID-19 tests, leading to reduced testing capacity and potential care delays.

The AAFP believes relying on complaints to determine a provider’s potential noncompliance could result in incorrect reports of noncompliance. A provider may have the information available on their website, but patients may inadvertently miss the information resulting in providers being incorrectly reported. The AAFP further believes CMS should send a second notice before requiring a CAP. Physician practices should have at least 45 calendar days from the date of the second notice to correct the violation before the practice is required to submit a CAP.

The AAFP is very concerned imposing a CMP will further threaten practices that are already struggling financially. The high levels of administrative work currently required of primary care practices may cause a notice of noncompliance to be missed or never received, resulting in large fines. Prior to the pandemic, small and independent practices were operating on thin margins and struggling to keep their doors open. These practices’ financial situations have been exacerbated by the PHE. The dollar amount of these fines per day would devastate a small family practice and possibly force it to close. In order to avoid the possibility of incurring a CMP, it is likely that some practices will instead stop offering COVID-19 tests. The AAFP believes a CMP should be nominal – no more than \$20 per day – and only imposed on practices with previous violations or CAPS.

Temporary Increase in Federal Medicaid Funding

The FFCRA includes a 6.2 percentage point increase in FMAP to help states respond to surges in Medicaid enrollment and service provision during the COVID-19 pandemic. In order to be eligible for this increase in the federal contribution to state Medicaid budgets, states were required to abide by a maintenance of effort (MOE) provision. According to guidance from CMS released in late March and updated in mid-April, states are prohibited under the MOE from disenrolling beneficiaries during the PHE.⁶ Specifically, in order to receive the enhanced FMAP, states must ensure that a beneficiary can continue to access the benefits package that was available to them as of March 18, 2020 (or a later date within the COVID-19 PHE) through the end of the month in which the PHE for COVID-19 ends.

In the IFR, CMS adopts an alternative interpretation of the MOE requirements set forth in the FFCRA. The agency indicates the new interpretation is due to concerns presented by states, which have indicated that the previous interpretation of the MOE requirements will result in a significant backlog of beneficiaries who are in the wrong eligibility group after the end of the PHE. Under the alternative interpretation, states would be required to make changes to a beneficiary's eligibility to reflect a change in income, age, pregnancy status, or other eligibility factors. States would still be unable to disenroll beneficiaries entirely and they would still be required to move beneficiaries into eligibility categories that provide more generous coverage if eligibility criteria are met.

CMS creates three tiers of coverage to guide states in moving beneficiaries between eligibility groups without violating the alternative interpretation of the FFCRA.

The first tier includes Medicaid coverage that meets the definition of minimum essential coverage. Under the first tier, states can move eligible beneficiaries into different eligibility groups as long as minimum essential coverage and access to COVID-19 testing and treatment is maintained for those who had it as of March 18, 2020. If the state determines a beneficiary is ineligible for the group in which they are currently enrolled, but are eligible for another group that provides minimum essential coverage, the state must transfer the beneficiary to the new group. However, states cannot move beneficiaries who had minimum essential coverage as of March 18, 2020 (or at a later date during the PHE) into an eligibility group that does not provide minimum essential coverage.

Under the second tier, states are permitted to move beneficiaries into different eligibility groups as long as coverage of COVID-19 testing and treatment is maintained. In addition, states must transition a beneficiary from tier 2 coverage to tier 1 coverage if that beneficiary becomes eligible for coverage that qualifies as minimum essential coverage.

The third tier applies to eligibility groups that do not provide minimum essential coverage or coverage of testing or treatment for COVID-19. If a beneficiary that is eligible for a type of tier 3 coverage becomes ineligible while the MOE requirements are in effect, the state cannot move them into a different tier 3 eligibility group because benefits would change significantly. However, the state is required to move a beneficiary into a tier 1 or tier 2 group if they become eligible.

CMS indicates in the IFR that, under the reinterpretation, states can reduce or eliminate optional benefits, apply prior authorization requirements, increase beneficiary liability, and increase cost sharing during the PHE without violating the requirements in the FFCRA for the 6.2 percent FMAP increase.

The AAFP is opposed to the alternative interpretation of the MOE requirements for states to be eligible to receive the 6.2 percent increase in federal matching funds, as set forth in FFCRA. We also are opposed to the new provisions allowing states to eliminate optional benefits, and reduce the amount, duration, and scope of covered benefits. We are deeply concerned that this approach will create confusion and administrative burden for family physicians, as well as jeopardize the health of their patients enrolled in state Medicaid plans. **The AAFP strongly urges CMS to abandon the alternative interpretation finalized in the IFR and instead reinstate the guidance on MOE requirements that was provided to states earlier this year.**

First, the alternative interpretation of the MOE requirements is not reflective of congressional intent since Medicaid beneficiaries can lose some benefits when they are moved between eligibility categories. The FFRCA clearly states that states cannot receive the 6.2 percent FMAP increase if:

“the State fails to provide that an individual who is enrolled for benefits under such plan (or waiver) as of the date of enactment of this section or enrolls for benefits under such plan (or waiver) during the period beginning on such date of enactment and ending the last day of the month in which the emergency period described in subsection (a) ends shall be treated as **eligible for such benefits** through the end of the month in which such emergency period ends unless the individual requests a voluntary termination of eligibility or the individual ceases to be a resident of the State”

This language does not indicate that only minimum essential coverage and COVID-19 testing and treatment benefits must be maintained – but that all benefits for which the beneficiary is enrolled beginning on March 18, 2020 must be maintained.

We appreciate the guardrails the agency has put in place to ensure that beneficiaries do not lose minimum essential coverage or coverage for testing and treatment of COVID-19. However, allowing states to move beneficiaries between benefit categories could result in loss of benefits that are not considered minimum essential coverage. For example, a beneficiary that turns 21 and is moved from the child eligibility category to the expansion eligibility category will lose the Early Periodic Screening Diagnostic and Treatment (EPSDT) benefit and may be unable to access necessary immunizations, such as the human papillomavirus vaccine. The AAFP does not believe that the FFRCA can be interpreted to allow for the loss of benefits like EPSDT.

Many Medicaid beneficiaries are at a higher risk, whether because they are more likely to contract COVID-19 or are at an elevated risk of having severe COVID-19 disease.⁷ Evidence indicates that Medicaid coverage expansions improve access to care and help to mitigate racial health disparities, which is vital as Black, Hispanic, and Indigenous people experience disproportionately higher COVID-19 infection and mortality rates.^{8,9,10} The AAFP maintains that consistent health care coverage is vital for Medicaid beneficiaries and to our pandemic response.

Moving beneficiaries between eligibility categories within a tier, as well as eliminating or limiting the scope of optional benefits, will also create confusion and additional burden for physicians as they try to determine what services are no longer covered for their patients. For example, some patients may no longer have coverage for prescription medications that they are dependent on. Physicians will need to counsel these patients on how to stay healthy if they cannot access medications and will

likely look for ways to help patients afford their medications. Many patients will need to be connected to community-based services to help fill coverage gaps and affordability concerns.

The alternative interpretation of the MOE requirements also allows states to impose prior authorization and other utilization management techniques that increase burdens on physicians and reduce timely access to care. The AAFP believes family physicians using appropriate clinical knowledge, training, and experience should be able to prescribe and/or order without being subjected to prior authorizations. A recent study found that primary care physicians spend about half of their time on administrative tasks, which was more time than they spent on clinical activities.¹¹ Increasing administrative tasks is especially harmful as family physicians are simultaneously serving on the frontlines of the COVID-19 pandemic and trying to make up for care that was missed due to the pandemic. The cost of fulfilling prior authorization requirements is significant, with many family physicians employing support staff for the express purpose of fulfilling prior authorizations. The AAFP is concerned that increasing the cost of caring for Medicaid beneficiaries will force physician practices to reduce their Medicaid patient panel and obstruct access to care. **We strongly recommend that CMS reverse its decision to allow the use of prior authorizations and other utilization management techniques for the duration of the PHE.**

We are also opposed to the provisions in the IFR that allow states to increase patients' liability and cost sharing during the PHE. According to the Bureau of Labor Statistics, more than 11 million people in the US are currently unemployed.¹² Many of these people have lost their source of income and employer-based health insurance coverage amid a surging pandemic. Evidence indicates that imposing even minimal cost-sharing on low-income people is associated with reduced use of necessary health care services.¹³ Medicaid cost sharing requirements also increase financial strain on physician practices and community health centers, which are already experiencing dramatic financial challenges due to the pandemic. Further, state savings from cost sharing are limited and are typically offset by other expenses. For all of these reasons, **we are opposed to the provision in the IFR allowing states to increase cost sharing during the PHE.**

The AAFP appreciates CMS' efforts to provide additional flexibility to states in order to avoid physician payment cuts and we agree that adequate Medicaid payment rates are vital to ensuring ongoing access to care for Medicaid beneficiaries. The AAFP has repeatedly encouraged Congress to increase the federal match for states for the duration of the PHE and we continue to believe this is the best way to support states as they grapple with budget shortfalls and growing Medicaid rolls.

Rapid Coverage of Preventive Services for Coronavirus by Private Payers

Scope of Requirement to Cover Certain Recommended Preventive Services under Section 2713 of the Public Health Service Act

CMS and the Departments state that under the 2015 Final Regulations and this IFR, plans and issuers subject to section 2713 of the Public Health Service (PHS) Act must cover, without cost sharing, items and services that are integral to the furnishing of the recommended preventive service, regardless of whether the item or service is billed separately. CMS further states that as qualifying coronavirus preventive services are expected to include immunizations, plans and issuers subject to section 2713 of the PHS Act must cover without cost sharing such an immunization and its administration, regardless of how the administration is billed, and regardless of whether a COVID-19

vaccine or any other immunization requires the administration of multiple doses in order to be considered a complete vaccination. This includes coverage without cost sharing of the administration of a required preventive immunization in instances where a third party, such as the federal government, pays for the preventive immunization. If a COVID-19 immunization is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the visit is the delivery of the recommended COVID-19 immunization, then consistent with the 2015 Final Regulations, the plan or issuer may not impose cost-sharing requirements with respect to the office visit. CMS seeks comment on this clarification.

AAFP Response

The AAFP appreciates and agrees with CMS' clarification on coverage of preventive services, the administration of multiple vaccine doses, coverage of the administration where a third party pays for the preventive immunization, and coverage of an office visit billed with the immunization. The AAFP believes this will alleviate payment questions and ensure physicians are paid appropriately for their services, as well as improve coverage and uptake of a COVID-19 vaccine among privately insured patients.

Out-of-Network Coverage During the PHE for COVID-19

The IFR provides that with respect to a qualifying coronavirus preventive service and a provider with whom the plan or issuer does not have a negotiated rate for such service (such as an out-of-network provider), the plan or issuer must reimburse the provider for such service in an amount that is reasonable, as determined in comparison to prevailing market rates for such service. CMS will consider the amount of payment to be reasonable, for example, if the plan or issuer pays the provider the amount that would be paid under Medicare for the item or service.

CMS requests comment on the issue of network adequacy and whether and, if so, how long provider networks are expected to be inadequate. CMS also requests comment on the safeguards in this IFR to ensure that out-of-network reimbursement rates are reasonable and that providers administering a publicly funded COVID-19 vaccine are reimbursed by group health plans and issuers prevailing market rates in the absence of a negotiated rate, and whether other examples of reasonable reimbursement rates, in addition to Medicare rates, would be useful.

AAFP Response

The AAFP agrees with CMS' decision that would require plans or issuers to cover a qualifying coronavirus preventive service without cost-sharing, regardless of whether such service is delivered by an in-network or out-of-network provider. The AAFP believes this should be extended through the end of calendar year 2022 to allow for the U.S. population to receive coronavirus preventive services without fear of being charged for out-of-network cost-sharing. In the absence of a negotiated rates, the AAFP believes plans and insurers should pay out-of-network physicians the average local negotiated rate of in-network physicians. Regardless of the payment mechanism, the AAFP believes all payment rates should be at least Medicare rates. In order to improve access to a COVID-19

vaccine without increasing burdens on physicians, the AAFP believes out-of-network physicians should be paid timely and in a similar manner to in-network physicians.

Diagnostic Testing for COVID-19

CMS notes that there have been wide variations in the time it takes providers to make COVID-19 test results available to consumers. These delays in obtaining test results increase the risk that infected individuals may unknowingly infect others. These delays could be caused by large volumes of tests to process and/or inadequate resources. Pay-for-performance arrangements, where reimbursement rates are based on the time it takes to make test results available, could encourage innovative approaches by providers to reduce the turnaround time. The Departments encourage group health plans and issuers of group or individual health insurance coverage to consider developing such arrangements with providers, and strongly encourage plans and issuers that do so to incorporate safeguards to ensure that the payment arrangements are not structured in a way that prioritizes speed over accuracy or that result in unintended consequences, such as reduction in access to COVID-19 diagnostic testing or noncompliance with balance billing restrictions.

AAFP Comment

The AAFP has concerns with pay-for-performance arrangements that are designed to reduce the time between when COVID-19 diagnostic tests are performed and when results are reported to patients. While we agree that timely reporting of test results is important for containing the spread of COVID-19, family physicians and their partners in laboratories report that resource constraints continue to be a significant barrier to diagnostic testing. While testing capacity has improved since earlier this year, labs are now reporting testing backlogs due to the increased COVID-19 case load and holiday season. Testing supply shortages have also impacted capacity. Physicians, labs, and other diagnostic test providers should not be punished for resource constraints and other issues that are beyond their control.

We are also concerned that implementing pay-for-performance arrangements could have other unintended consequences, such as causing labs to de-prioritize other types of tests that are critically important for the health of patients. For example, family medicine practices are currently experiencing delays in receiving results for sexually transmitted infections. While the timely reporting of COVID-19 test results is important for containing the spread of the virus, other types of lab results are also essential to appropriately treating acute illnesses or managing chronic conditions.

State Innovation Waivers Policy and Regulatory Revisions in Response to the PHE for COVID-19 Public Health Emergency

HHS and Treasury will allow states to request that state and federal public notice requirements for 1332 waivers are waived during the PHE if certain conditions are met. For example, states can submit requests to modify the length of the public comment period or bypass the requirement to hold multiple hearings before submitting an application for a 1332 waiver. The IFR also allows HHS and Treasury to waive public notice requirements for approved 1332 waivers during the PHE for COVID-19 when the application of the public notice procedures would be contrary to the interests of the consumers.

AAFP Comment

The AAFP opposes this regulatory revision and we encourage HHS and Treasury to reverse it. **Public notice requirements, including state and federal comment periods, are essential for properly assessing the impact of proposed 1332 waivers.** States can make significant changes using their 1332 waiver authority and the myriad of stakeholders that could be impacted by the proposed changes should have ample time to analyze and provide comments to the state and federal agencies.

States already have 1135 waiver authority for the explicit purpose of making rapid changes in the event of a public health emergency. Most states have used this authority during the COVID-19 pandemic. The AAFP commends CMS for working with states to ensure that they could quickly respond to this crisis. However, we do not support the changes made to the 1332 waiver process set forth in this IFR.

Thank you for the opportunity to provide comments on the interim final rule. Should you have any questions, please contact Meredith Yinger, Senior Regulatory Strategist, at myinger@aafp.org or 202-235-5126.

Sincerely,



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