December 18, 2020

Seema Verma
Administrator
Department of Health and Human Services
Centers for Medicare & Medicaid Services
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (CMS-9912-IFC)

Dear Administrator Verma:

Thank you for the opportunity to comment on CMS-9912-IFC, "Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" (hereinafter referred to as "the IFC").

The undersigned organizations represent millions of patients facing serious, acute, and chronic health conditions across the country. Our organizations have a unique perspective on what patients need to prevent disease, cure illness, and manage chronic health conditions. Our diversity enables us to draw upon a wealth of knowledge and expertise that can be an invaluable resource in this discussion. We urge the Department of Health and Human Services (HHS) to make the best use of the knowledge and experience our patients and organizations offer in response to this proposed rule.

In March of 2017, our organizations agreed upon three overarching principles[1] to guide any work to reform and improve the nation's healthcare system. These principles state that: (1) healthcare should be

accessible, meaning that coverage should be easy to understand and not pose a barrier to care; (2) healthcare should be affordable, enabling patients to access the treatments they need to live healthy and productive lives; and (3) healthcare must be adequate, meaning healthcare coverage should cover treatments patients need, including all the services in the essential health benefit (EHB) package.

Our organizations are deeply concerned by the IFC provisions related to the Families First Coronavirus Response Act (FFCRA) Medicaid maintenance of effort (MOE) provisions and those allowing states to circumvent required transparency procedures for §1332 waivers. And while we appreciate some of the steps that CMS has taken to extend coverage of a COVID-19 vaccine without cost-sharing, we continue to have concerns about critical gaps in coverage, including vaccine coverage for the patients we represent. We urge the Department to rescind the provisions at 42 CFR §433.400 and return to the correct interpretation of the conditions states must comply with in exchange for the additional 6.2 percentage point increase in the Federal Medical Assistance Percentage (FMAP) that were laid out in CMS guidance following passage of the FFCRA. The Department should also rescind the provisions at 42 CFR Part 155 related to §1332 waiver transparency rules.

Medicaid Coverage and Financing during the Public Health Emergency

The FFCRA provided a temporary 6.2 percentage point increase in the FMAP through the end of the calendar year quarter in which the current public health emergency (PHE) expires. In October 2020, the Secretary of Health and Human Services (HHS) extended the PHE through January 20, 2021, therefore the FMAP increase remains in effect through at least March 31, 2021.

As a condition of receiving the increased FMAP, state Medicaid programs must not implement eligibility standards, methodologies and procedures that are more restrictive or charge higher premiums than were in place on January 1, 2020 (FFCRA §6008(b)(1)-(2)). They must cover COVID-19 testing and treatment without cost-sharing (FFCRA §6008(b)(4)). They must also maintain coverage for any beneficiaries who were enrolled as of March 18, 2020 (or newly enrolled beneficiaries after such date) through the end of the month in which the PHE ends; thus, state Medicaid programs currently must maintain enrollment through at least January 31, 2021 (FFCRA §6008(b)(3)). These MOE provisions, and especially the last "continuous coverage" requirement, are critical to ensuring that low-income individuals and families have access to health coverage and needed care during the pandemic.

Medicaid is a countercyclical program; enrollment and spending rise when the economy declines, compounding state budget and revenue woes. As in past recessions, Congress enacted the FMAP increase to provide states with additional federal support to sustain Medicaid at a time when states would otherwise struggle to maintain needed access to care. Since the FFCRA FMAP increase took effect, states have successfully drawn down tens of billions of dollars in federal funds, and the Congressional Budget Office (CBO) estimates that the 6.2 percentage point FMAP increase will be worth about $30 billion to states in 2021.[2] As a condition of giving states additional federal funds, Congress included the maintenance of effort and continuous coverage provisions noted above in order to hold beneficiaries harmless against the loss of coverage or benefits during the pandemic.

Earlier this year, in Frequently Asked Questions (FAQ) guidance documents to states, CMS interpreted the continuous coverage requirement as barring states from cutting benefits or increasing cost-sharing for Medicaid beneficiaries while they are enrolled.[3] This is consistent with the plain reading of the FFCRA statutory language, which requires that a state would no longer be eligible for the 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…" (See FFCRA §6008(b)(3), emphasis added.)

In other words, it would constitute a violation of the continuous coverage requirement and make a state ineligible for the 6.2 percentage point FMAP increase if the state eliminated or scaled back a beneficiary's benefits or increased their cost-sharing. This interpretation should be reinstated.

The IFC reverses CMS' earlier, sound reading of the continuous coverage requirement and 42 CFR §433.400 should be rescinded. Specifically, the IFC violates the plain reading of the statute with respect to: (1) maintaining benefits, (2) beneficiary financial liability, (3) requiring beneficiaries to be "validly enrolled," (4) maintaining comprehensive coverage for lawfully residing children and pregnant women, and (5) requiring coverage of COVID-19 vaccines in Medicaid. The Secretary of HHS does not have the authority to rewrite the statute and add categories and tiers where none exist.

Benefits

Under the IFC, state Medicaid programs are permitted to eliminate optional benefits such as adult dental, vision, and prescription drug coverage and home and community-based services (HCBS) and reduce the amount, duration and scope of covered benefits (such as imposing lower visit limits or adding other utilization controls), compared to what was covered on March 18, 2020, even as they continue to collect an additional 6.2 percentage points of federal matching funds. Eliminating optional benefits would clearly violate the statutory requirement that beneficiaries continue to receive *such benefits* as they received in January – March 2020 (or, if enrolled after March 18, 2020, the benefits received at the time of enrollment) through the end of the month in which the PHE ends as a condition of receiving the higher federal match. Similarly, allowing states to reduce the scope of services covered would mean beneficiaries no longer receive *such benefits*. These benefit changes could have particularly harmful consequences for beneficiaries managing a chronic condition or for those in the middle of a course of treatment, and a pause or delay in treatment could result in worse health outcomes including their disease worsening irreversibly. For example, people with epilepsy who experience a disruption in access to their prescription drug regimen are at higher risk of seizure recurrence, hospitalization, and other health complications.[4] Cancer patients undergoing an active course of treatment for a life-threatening health condition need uninterrupted access to the providers and facilities from whom they receive treatment. Disruptions in primary cancer treatment care, as well as longer-term adjuvant therapy, such as hormone therapy, can result in negative health outcomes. Additionally, recent cancer survivors often require frequent follow-up visits and maintenance medications as part of their survivorship care plan to prevent recurrence,[5] and suffer from multiple comorbidities linked to their cancer treatments.[6]

Therefore, 42 CFR §433.400(c)(3) should be rescinded and CMS should reinstate the correct interpretation barring reductions in benefit as laid out in the April FAQ (*See* Increased FMAP FAQ #B12, updated as of April 13, 2020). It is clear from the statutory language that Congress intended to ensure Medicaid beneficiaries maintain coverage and access to needed services during the pandemic in exchange for the additional federal funding.

The IFC would also permit states to transfer beneficiaries from one eligibility category to another if they are no longer eligible under their original category, even if it may reduce the benefits available to them. The IFC would limit such changes to other eligibility categories with benefits in the same "tier." But, for example, under this erroneous interpretation of the statute, the continuous enrollment protection would no longer require states to provide young people with the comprehensive Early Periodic Screening Diagnostic and Treatment (EPSDT) benefit as they turn 21. Similarly, a near-elderly Medicaid beneficiary who turns 65 and becomes eligible for Medicare could be switched to the Medicare Savings Programs, losing access to some Medicaid benefits that may not be covered by Medicare. Furthermore, many people receive HCBS benefits that keep them in their homes and communities and out of institutional settings. Under this new interpretation, if an individual loses financial eligibility for HCBS under at 1915(c) waiver he or she would be transferred to the Medicaid Expansion, which generally does not cover HCBS provided by a 1915(c) waiver. Loss of the HCBS that keep a person safe at home creates risk of falls, missed medications, and other complications that can result in hospitalization and institutionalization. Due to this changed interpretation, a person with a disability could go from receiving HCBS safely at home to being at risk of COVID-19 infection in a hospital or other institution. This IFC's tiering provision is in direct conflict with the statutory requirement noted above ensuring beneficiaries continue to receive the same benefits through the end of the month in which the PHE ends as a condition of receiving the additional federal funds.

The IFC attempts to justify these changes by describing an alternative approach or "enrollment interpretation" that would *require* states to move beneficiaries to different eligibility groups, even if the new group confers lesser benefits or results in higher cost-sharing. The "enrollment interpretation" clearly violates the statutory standard and would tie the hands of states that would prefer to minimize administrative burdens and keep beneficiaries enrolled in the original category even if their eligibility category has since changed. Describing this alternative, enrollment interpretation that is clearly outside the parameters laid out in the statute does not make the adopted, "blended" approach more lawful or sensible.

The IFC would also allow states to terminate coverage for Medicaid beneficiaries if they do not respond to requests to verify residency following a data match indicating simultaneous Medicaid enrollment in two or more states (42 CFR §433.400(d)(3)(ii)). The FFCRA continuous coverage provision does not provide for the disenrollment of beneficiaries unless the beneficiary requests a voluntary termination or ceases to be a state resident. A possible discrepancy on state residency is not grounds for disenrollment. Even before the pandemic, Medicaid beneficiaries struggle to maintain coverage during redetermination periods because of lost or delayed mailings.[7] These challenges have been exacerbated by the PHE and are precisely why Congress acted to ensure continuous coverage despite possible changes in circumstances. For example, states are already reporting an increase in returned mail due to the pandemic.[8] Serious health, economic, or housing problems are expected to contribute to procedural problems for states but are not grounds for terminating coverage while receiving the enhanced federal funding under FFCRA. CMS should instead work with states and encourage states to work with each other to resolve any possible discrepancies on state residency.

The IFC accurately interprets the statute with respect to two benefits issues: (1) if an individual is found ineligible for all Medicaid eligibility categories, states are required to keep that beneficiary enrolled in the original eligibility category with the benefits that are otherwise available to that category (42 CFR §433.400(c)(2)(iv)); and (2) beneficiaries must always be transferred to a more generous level of benefits if eligible (85 FR 71165).

Our organizations urge CMS to rescind the provisions laid out in 42 CFR §433.400(c)(2)(i) and (ii) and reinstate the interpretation laid out in FAQ that required states to cover beneficiaries in the eligibility group with the most generous benefits the beneficiary is eligible for and maintain access to all such services through the end of the month in which the PHE ends as the statute requires (*See* Increased FMAP FAQ #B6, B11, and B12, updated as of April 13, 2020).

Beneficiary Financial Liability

The IFC also reverses CMS' earlier guidance with respect to cost sharing, in plain violation of the statute. In the COVID-19 FAQ first issued in early April 2020 and updated over the summer, CMS wrote that increasing cost-sharing amounts would violate the FFCRA continuous coverage provision because, "an increase in cost-sharing reduces the amount of medical assistance for which an individual is eligible." (p.29) The FAQ also clearly prohibited changes to post eligibility treatment of income (PETI) rules, stating that, "Like cost-sharing increases, increasing a beneficiary's liability reduces the amount of medical assistance for which an individual is eligible and is therefore inconsistent with the requirement at section 6008(b)(3) of the FFCRA." (p. 30)

Even small increases in cost-sharing imposed on low-income populations are associated with reduced use of care, including necessary services.[9] Early on in the pandemic, outpatient visits declined precipitously; overall outpatient visits declined by about 60 percent with even bigger declines for children.[10] Even as some visits have returned to pre-pandemic levels, others still lag behind, including visits by Medicaid patients.[11] Moreover, the economic crisis brought on by the pandemic has made it increasingly hard for families to make ends meet. Even in the early weeks of the pandemic, over two-thirds (68.6 percent) of adults with family incomes below the federal poverty level and over 45 percent of black and Hispanic adults reported that their families could not pay the rent, mortgage, or utility bills, were food insecure, or went without medical care because of cost.[12] Allowing states to continue to receive the enhanced federal funding while imposing higher cost sharing not only violates the plain reading of the statute, it would exacerbate these problems for families and widen racial and ethnic inequities.

Under the IFC, states may add or increase cost-sharing and beneficiary liability under the state's PETI rules even though it is clear that such increases would constitute a reduction in benefits in violation of the statute. Requiring nursing home residents or recipients of HCBS to contribute more to the monthly cost of their care above what was required on March 18, 2020 not only violates the statute, but cruelly targets a group that has already been disproportionally harmed by the pandemic and continues to be at great risk. Long-term care facilities account for 40% of all COVID-19 deaths,[13] and nursing home residents are struggling with isolation from family and friends.[14] Increases in cost sharing could push HCBS recipients into facilities, putting them at greater risk of contracting COVID-19.

CMS should rescind 42 CFR §433.400(c)(3) and return to the interpretation in the FAQ that prevents states from increasing cost-sharing and other financial obligations during the period that states are accepting the 6.2 percentage point FMAP increase (*See* COVID-19 FAQ #I3 and I4, updated as of June 30, 2020).

Validly enrolled

CMS indicates that a state would not be out of compliance with the continuous coverage requirement if it disenrolls a beneficiary who was not "validly enrolled" in the first place (the eligibility determination was erroneous or the result of fraud and abuse). While CMS has indicated that generally beneficiaries are considered "validly enrolled," the IFC fails to explain how "invalidly" enrolled beneficiaries would be

identified, nor does it provide for any protection against unreasonably requiring beneficiaries to document their valid enrollment repeatedly. The Secretary should limit any allowable disenrollment to only those beneficiaries who have been convicted of or pleaded guilty to fraudulent enrollment (as defined by 42 §CFR 455.2).

Maintaining coverage for lawfully residing immigrant children and pregnant women
Under SSA §1903(v)(4), states have the option to provide coverage to lawfully residing immigrant children and pregnant women during their first five years in the U.S. As of January 2020, 35 of 51 states and DC have adopted this option for children in Medicaid, 24 of 35 have adopted this option for children in separate CHIP programs, 25 of 51 have adopted this option for pregnant women in Medicaid, and 4 of 6 have adopted this option for pregnant women in CHIP.[15] The FFCRA provisions requiring continuous coverage are inclusive of all beneficiaries enrolled as of March 18, 2020, and those who have enrolled since that date, and there is no distinction made for beneficiaries enrolled under the state option at §1903(v)(4). The only two exceptions to the continuous coverage requirement are a voluntary request for disenrollment by the beneficiary and when a beneficiary is no longer a state resident. The Secretary of HHS does not have the authority to make the exception at 42 CFR §433.400(d)(2) while states continue to receive the extra federal funding.

Under the IFC, states that have opted to cover lawfully residing children and pregnant women would be *required* to limit their coverage to emergency services if individuals are found to no longer meet the definition of such children and pregnant women. The IFC does not elaborate on how such children and pregnant women would be identified nor whether they would have a reasonable opportunity to provide any needed documentation of their ongoing eligibility. Under this misinterpretation of the statute, states must disenroll lawfully residing children who reach age 21 and lawfully residing women who are no longer pregnant, in contradiction to the plain reading of the statute requiring continuous coverage for all beneficiaries enrolled. CMS should rescind 42 CFR §433.400(d)(2).

COVID-19 Vaccine Coverage

Our organizations appreciate CMS implementing the FFCRA vaccine coverage policy for most individuals without cost-sharing. Specifically, we support the provisions in the IFC to require most private insurance plans to cover administration of COVID-19 vaccines (as well as the vaccines themselves) without cost-sharing and to waive patients' cost-sharing even if vaccines are administered by out-of-network providers.[16] However, critical gaps in vaccine coverage still remain.

Non-Compliant Plans
Patients enrolled in private health insurance plans that do not comply with the ACA's coverage requirements – including grandfathered health plans, short-term limited duration plans and association health plans – may not have coverage for a COVID-19 vaccine or be charged significant cost-sharing. Our organizations have repeatedly shared our concerns about the growth of non-compliant plans and the risks they pose to the patients we represent.[17] These plans put enrollees at substantial financial and physical risk. Despite Congressional and administrative action to ensure COVID-19 vaccination be provided at no-cost to promote the public health, Americans enrolled in insurance-like products will not be protected. For example, the Commonwealth Fund found that short-term plans have significant coverage gaps that would extend to COVID-19 vaccines.[18] If a non-compliant plan doesn't cover the COVID-19 vaccine, enrollees should be considered uninsured and therefore receive the vaccination without cost-sharing.

Medicaid

The FFCRA requires states to cover COVID-19 testing and treatment, including vaccines, specialized equipment, and therapies without cost-sharing (FFCRA §6008(b)(4)) through the end of the quarter in which the PHE ends, as a condition of receipt of the higher federal match. The statute does not make any exceptions to this requirement or limit it to only certain eligibility groups. However, under the IFC, states would be permitted to continue to receive the extra federal funding even if they do not provide COVID-19 testing, treatment and vaccine coverage to all Medicaid beneficiaries, in violation of the plain reading of the statute. CMS specifically invites states to limit access to COVID-19 vaccines in Medicaid by excluding such coverage for people enrolled in Medicaid limited benefit plans. For example, beneficiaries enrolled in programs focused on the treatment of breast and cervical cancer and tuberculosis, family planning programs, and some programs provided under §1115 waiver authority, would not have access to COVID-19 vaccines even as the state continues to draw down the additional federal funding.

The FFCRA makes no such distinction between full and limited Medicaid benefit categories, and specifically applies the requirement to §1115 waiver programs. The Secretary does not have the authority to allow states to continue to receive the enhanced federal funding without complying the provisions as laid out in FFCRA §6008(b)(4). Many of the patients we represent have underlying medical conditions that put them at increased risk for severe illness from COVID-19, and it is critical that patients in the Medicaid program have coverage of COVID-19 vaccines regardless of their benefit package.

Finally, our organizations remain concerned that COVID-19 vaccine coverage for adults in the traditional Medicaid population will still be optional for state Medicaid programs after the end of the public health emergency.[19]

1332 Waiver Changes

Under §1332 of the Affordable Care Act (ACA), states may apply for a State Innovation Waiver to alter key ACA requirements in the individual and small group health insurance markets. States must demonstrate compliance with four statutory requirements for §1332 waivers to be approved: (1)coverage that is at least as comprehensive in covered benefits and (2) at least as affordable, reaching (3) at least a comparable number of state residents and (4) without increasing the federal deficit. The statute also requires states and the federal government to provide the public with an opportunity to comment. To date, most states have used §1332 waivers to create reinsurance programs and improve affordability in the marketplace, but recent §1332 waiver proposals and approvals fail to meet the statutory requirements laid out above.[20]

Under the IFC, CMS would go even further by allowing the "modification" of public notice, comment and hearing requirements for §1332 waiver proposals, including allowing the state public notice and comment period to come *after* the state files its application and the federal comment period to come *after* CMS conducts its review during the PHE. The Secretary does not have the authority to bypass the statutory requirements related to meaningful stakeholder input in waiver policy. Our organizations rely on the public comment process to provide feedback on how waiver proposals will impact our patients and other key stakeholders and we urge the Administration to rescind these provisions of the IFC.

IFC Unjustifiably Vitiates Meaningful Public Comment

Notably, while CMS issued its original interpretation of the continuous coverage requirement as guidance in April, and left it undisturbed for eight months, it is now reversing it through an interim final rule that went into effect immediately upon public display on November 2, 2020. The IFC unjustifiably takes away meaningful public comment as these changes will already be in effect well before any public comments are submitted, let alone considered. There is no significant urgency for the policies at 42 CFR §433.400, especially given the earlier guidance from CMS on the MOE that has been in place since April 2020, whereas reducing health care eligibility, decreasing benefits, and increasing costs during a pandemic is clearly contrary to the public interest.

Conclusion

The Secretary does not have the authority to allow states to continue to receive the 6.2 percentage point FMAP increase without complying with the statutory maintenance of effort and continuous coverage provisions in section 6008 of FFCRA. Therefore, CMS should rescind 42 CFR §433.400 and reinstate the policies as laid out in earlier guidance. CMS should also continue to enforce the public notice and comment period requirements for §1332 waivers.

Thank you again for the opportunity to comment. Please contact Theresa Alban of the Cystic Fibrosis Foundation at talban@cff.org if you have any questions or if we can be of further assistance.

Respectfully submitted,

Alpha-1 Foundation
American Cancer Society Cancer Action Network
American Heart Association
American Kidney Fund
American Lung Association
Arthritis Foundation
Asthma and Allergy Foundation of America
Cancer Support Community
Cancer*Care*
Cystic Fibrosis Foundation
Epilepsy Foundation
Family Voices
Hemophilia Federation of America
March of Dimes
Muscular Dystrophy Association
National Alliance on Mental Illness
National Health Council
National Hemophilia Foundation
National Multiple Sclerosis Society
National Organization for Rare Disorders
National Patient Advocate Foundation
Pulmonary Hypertension Association
Susan G. Komen
The AIDS Institute
The Leukemia & Lymphoma Society

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