January 4, 2020

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9912-IFC
P.O. Box 8016
Baltimore, MD 21244-8016

RE: Comments on CMS-9912-IFC
Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency

Dear Administrator Verma:

The National Health Law Program (NHeLP) is a public interest law firm working to advance access to quality health care and protect the legal rights of low-income and underserved people. We appreciate the opportunity to provide these comments on the Centers for Medicare and Medicaid Services' (CMS) interim final regulation (IFR), Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency.

NHeLP recommends that CMS retract and not finalize several provisions of the IFR that raise legal concerns and would cause great harm to Medicaid enrollees. These changes are not in keeping with the letter and intent of Congress's laws, most notably the Families First Coronavirus Response Act (FFCRA), which was intended to protect coverage for Medicaid enrollees during a public health emergency – a devastating pandemic that is coupled with historic employment losses.

I. Procedural Concerns

From March to October 2020, CMS consistently and repeatedly interpreted the FFCRA Maintenance of Effort (MOE) provision to protect eligibility *and* benefits, as the law requires. CMS issued three guidances, two of which were updated and re-released, confirming this interpretation. These guidances explicitly interpreted the FFCRA statute to include services, and specifically

referenced amount, duration, and scope and affordability in some guidances. For example, CMS wrote that increasing cost-sharing for services would be "inconsistent with the requirement at § 6008(b)(3) of the FFCRA that the state ensure that beneficiaries be treated as eligible for the benefits in which they were enrolled." Yet, in October's IFR, despite increasing COVID-19 infections, CMS suddenly reversed course and implemented the *opposite* interpretation of the *same* law—whose wording had not changed. The apparent catalyst for change, identified in the preamble to the regulation, is that "states requested increased flexibility" – an inadequate basis on which to change a consequential legal interpretation.

Further, we do not believe these IFR policies -- which directly and materially access to health care for tens of millions of enrollees during a pandemic -- should have been implemented as an interim final rule. The Administrative Procedure Act anticipates that that government agencies will implement regulations only after receiving and considering public comment and that interim final rules will be used rarely and only of necessity -- for example when a comment period would be "contrary to the public interest."[1] There is no significant exigency associated with a notice and comment period for this IFR policy, whereas reducing health care eligibility, decreasing benefits, and increasing costs during a pandemic without an opportunity for prior comment will lead to immediate harms and is clearly contrary to the public interest. These policies will cause substantial harms before CMS has time to finalize the rule -- harms that could have been avoided had CMS solicited public comments, like ours, before the rule went into effect.

II. FFCRA Maintenance of Effort Interpretation

The Families First Coronavirus Response Act, which was signed into law on March 18, includes an option for states to receive enhanced federal Medicaid funding. In exchange for the additional funds, states must agree to comply with strong maintenance of effort (MOE) protections. These protections help ensure individuals are able to get and stay covered during the crisis and receive needed services.

As part of the MOE, under § 6008(b)(3), the state must treat anyone enrolled for Medicaid benefits as of March 18, 2020, or who enrolls during the public health emergency, as "eligible for **such benefits** through the end of the month" in which the public health emergency ends (emphasis added). This provision is an explicit requirement to preserve enrollee's existing benefits -- both their enrollment in Medicaid *and* the services they have been eligible for (including the amount, duration, and scope of benefits and affordability protections). At a time of such turmoil, Congress chose to protect enrollees and ensure access to services by maintaining the "status quo."

This IFR allows numerous types of coverage restrictions for individuals who are enrolled in Medicaid, including reduced benefits, reduced amount, duration, and scope

[1] 5 U.S.C. § 553(b)(3)(B).

of services, increased cost-sharing, and reduced post-eligibility income. All of these coverage reductions are barred by § 6008(b)(3). The policy will also result in terminations for some individuals who should not be terminated under § 6008(b)(3).

Reduction of Benefits

This rule gives states sweeping authority to reduce optional Medicaid benefits, cut the amount, duration and scope of benefits, increase utilization management, increase cost-sharing, and reduce post-eligibility income -- all with no consequences for their enhanced matching funds under FFCRA. These changes contravene the clear words and intent of the statute, and will result in significant harm for enrollees.

Optional Medicaid benefits include essential services like physical and occupational therapy, dental and vision services, and home and community-based services (HCBS). After the previous economic downturn in 2008, many states made significant cuts to each of these services.[2] Cuts to these services will cause significant harm. For example, untreated vision and dental issues contribute to poor overall health and hurt the economy.[3] Lack of Medicaid coverage for vision services makes it more likely that a person will have functional limitations.[4] Cutting Medicaid dental benefits makes little economic sense for states.[5] This is especially true during a pandemic; cutting dental

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[2] Vernon Smith et al., Health Management Associates and Kaiser Family Found., *Moving Ahead Amid Fiscal Challenges: A Look at Medicaid Spending, Coverage and Policy Trends* 93 (2011), https://www.kff.org/wp-content/uploads/2013/01/8248.pdf; MACPAC, Medicaid Coverage of Dental Benefits for Adults (2015), https://www.macpac.gov/wp-content/uploads/2015/06/Medicaid-Coverage-of-Dental-Benefits-for-Adults.pdf.

[3] Mayo Clinic, Oral health: A window to your overall health, June 4, 2019, https://www.mayoclinic.org/healthy-lifestyle/adult-health/in-depth/dental/art-20047475; U.S. Department of Health and Human Services Centers for Disease Control and Prevention, *Looking Ahead: Improving Our Vision for the Future*, last reviewed December 18, 2020, https://www.cdc.gov/visionhealth/resources/infographics/future.html; Elizabeth Hinton and Julia Paradise, Kaiser Family Found., *Access to Dental Care in Medicaid: Spotlight on Nonelderly Adults* (Mar. 2016), https://www.kff.org/medicaid/issue-brief/access-to-dental-care-in-medicaid-spotlight-on-nonelderly-adults; Dep't of Health & Human Servs., U.S. Pub. Health Serv., *Oral Health in America: A Report of the Surgeon General* (2000), https://www.nidcr.nih.gov/sites/default/files/2017-10/hck1ocv.%40www.surgeon.fullrpt.pdf; Janice S. Lee and Martha J. Sommerman, *The Importance of Oral Health in Comprehensive Health Care*, 320 JAMA 339 (July 24/31, 2018); National Institute of Medicine and National Research Council of the National Academies, *Improving to Oral Health Care for Vulnerable and Underserved Populations* (2011), https://www.hrsa.gov/sites/default/files/publichealth/clinical/oralhealth/improvingaccess.pdf; Rein DB, et al., *The economic burden of major adult visual disorders in the United States*, ARCH.OPHTHALMOL.1754–1760 (2006); Am. Dental Ass'n, Health Policy Inst., *Oral Health and Well-Being in the United States* (2015), https://www.ada.org/~/media/ADA/Science%20and%20Research/HPI/OralHealthWell-Being-StateFacts/US-Oral-Health-Well-Being.pdf?la=en.

[4] Brandy J. Lipton & Sandra L. Decker, *The effect of health insurance coverage on medical care utilization and health outcomes: Evidence from Medicaid adult vision benefits,* 44 J. HEALTH ECON. 320 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6767617/.

[5] Pew Ctr.on the States, *A Costly Dental Destination: Hospital Care Means States Pay Dearly* 1, 3 (2012), http://www.pewtrusts.org/-/media/assets/2012/01/16/a-costly-dental-destination.pdf; Cassandra Yarbrough et al.,*Estimating the Cost of Introducing a Medicaid Adult Dental Benefit in 22 States*, American Dental

services has been found to increase emergency department use for dental complaints -- a health care inefficiency particularly concerning effect during the pandemic, when many emergency departments are overrun and the risk of COVID-19 transmission is a major concern.[6]

Under financial strain, states are also likely to make cuts to HCBS because they represent a significant amount of state optional spending.[7] Almost all HCBS spending is optional.[8] Medicaid HCBS provides a broad and critical range of services to a wide range of individuals with different disabilities or health conditions and older adults.[9] Medicaid HCBS also help such individuals remain independent, avoid institutionalization, and remain integrated in their families and communities.[10] Under the IFR policy, states looking to save dollars will have incentives to make cuts to various populations with disabilities, including individuals with intellectual and developmental disabilities.[11] Cuts to HCBS services may serve states' short term budget needs, but likely increase costs over the long term.[12]

CMS justifies the IFR by stating that states may cut provider rates if they cannot cut benefits, and that "such rate cuts, combined with a substantially lower volume of visits since the beginning of the pandemic, could put some providers out of business".[13] However, cuts to optional benefits are also a major financial loss for providers, and many providers of optional benefits are especially likely to be facing financial strain due

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Association 2 (2016), http://www.ada.org/~/media/ADA/Science%20and%20Research/HPI/Files/HPIBrief_0316_1.ashx;

[6] Astha Singhal et al., *Eliminating Medicaid Dental Adult Coverage in California Led to Increased Dental Emergency Visits and Associated Costs*, 34 HEALTH AFF. 749 (2015), https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1358; Melissa Burroughs, Families USA, *California's Proposed Oral Health Cuts Would Cost the State Billions, Further Harm Those Hardest Hit by COVID-19* (May 2019), https://familiesusa.org/wp-content/uploads/2020/05/OH_Oral-Health-Medicaid-Budget-Cut-Fact-Sheet_5-28-20.pdf.

[7] Judith Solomon and Jessica Schubel, Center on Budget and Policy Priorities, *Medicaid Cuts in House ACA Repeal Bill Would Limit Availability of Home- and Community-Based Services* (Mar. 2017), https://www.cbpp.org/research/health/medicaid-cuts-in-house-aca-repeal-bill-would-limit-availability-of-home-and.

[8] Molly O'Malley Watts, Kaiser Family Foundation, *Medicaid Home and Community-Based Services Enrollment and Spending* (Feb. 2020), https://www.kff.org/report-section/medicaid-home-and-community-based-services-enrollment-and-spending-issue-brief.

[9] Mary Sowers et al., Kaiser Family Foundation, *Streamlining Medicaid Home and Community-Based Services: Key Policy Questions* (Mar. 2016), https://www.kff.org/report-section/streamlining-medicaid-home-and-community-based-services-key-policy-questions-issue-brief; Office of the Assistant Secretary for Planning & Evaluation, Understanding Medicaid Home and Community Services: A Primer (2010), https://aspe.hhs.gov/system/files/pdf/76201/primer10.pdf.

[10] *Id*.

[11] Jennifer Lav, National Health Law Program, *How Proposed Health Care Cuts Would Harm Care for People with Intellectual & Developmental Disabilities*, (June 2017), https://healthlaw.org/how-proposed-health-care-cuts-would-harm-care-for-people-with-intellectual-a-developmental-disabilities.

[12] Enid Kassner et al., AARP Public Policy Institute, *Taking the Long View: Investing in Medicaid Home and Community-Based Services Is Cost-Effective* (2009), https://assets.aarp.org/rgcenter/il/i26_hcbs.pdf.

[13] 85 Fed. Reg. 71161 (Nov. 6, 2020).

to the pandemic. For example, dental spending has fallen during the pandemic by far more than other provider types.[14] And among home and community-based service providers serving individuals with intellectual and developmental disabilities, 77% have had to close one or more programs, and 16% do not anticipate these programs reopening.[15]

Enrollees will also suffer due to cuts in the amount, duration, and scope of services. Such cuts could impact an incredibly wide range of services. For example, historically some states have placed numerical caps on benefits like physician services. Many states capped visits at just 12 a year.[16] While such capped services may be adequate for some enrollees, they will not be sufficient for other populations, such as many people with chronic illnesses and disabilities.

Prior authorizations and other utilization management requirements, which would be allowed under the IFR, can harm Medicaid enrollees and providers in typical times, and these issues are likely to be significantly exacerbated during COVID-19. Research has found that patients are more likely to discontinue needed medications when prior authorizations are required.[17] Further, a survey of certain Medicaid-enrolled providers in Texas found that they saw prior authorizations as a significant burden. They agreed that prior authorizations take time away from patients, and reduce the pool of providers that will see Medicaid patients due to administrative burden.[18] Presently, many providers are overwhelmed caring for COVID-19 patients.[19] Increased prior authorizations will divert them from that essential work. Moreover, overloaded physician offices and limited in-person visits make it more likely patients will "fall through the cracks" and not get their medications or other services when a prior authorization is needed. This concern is backed up by survey research, which reports

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[14] Michelle Millerick & Robert Nelb, Medicaid & CHIP Payment and Access Comm'n, *Relief Funding for Medicaid Providers Affected by the Pandemic* 4 (2020), https://www.macpac.gov/wp-content/uploads/2020/09/Relief-Funding-for-Medicaid-Providers-Affected-by-the-COVID-19-Pandemic.pdf.

[15] ANCOR, *COVID-19-Related Losses and Increased Expenses: July 2020 Data on the Fiscal Impact of COVID-19* 2 (2020), https://www.ancor.org/sites/default/files/exec_summary_july_2020_survey_of_the_fiscal_impact_of_covid-19_on_ancor_members.pdf.

[16] Kaiser Fam. Found., Medicaid Benefits: Physician Services, 2012, https://www.kff.org/medicaid/state-indicator/physician-services/?currentTimeframe=1&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (last visited Dec. 2, 2020).

[17] Stephen B. Soumerai et al., *Use of Atypical Antipsychotic Drugs for Schizophrenia in Maine Medicaid Following a Policy Change* 27 HEALTH AFF. (supplement 1) 185 (2008), https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.27.3.w185; Darshan Mehta et al., *Impact of Formulary Restrictions on Antiepileptic Drug Dispensation Outcomes* 9 NEUROLOGY AND THERAPY 505 (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7606428/pdf/40120_2020_Article_195.pdf.

[18] Carolyn M. Brown et al., *Development of the burden of prior authorization of psychotherapeutics (BoPAP) scale to assess the effects of prior authorization among Texas Medicaid providers* 36 ADMIN. AND POL'Y IN MENTAL HEALTH 278 (2009).

[19] Reed Abelson, *Covid Overload: U.S. Hospitals Are Running Out of Beds for Patients,* N.Y. Times (Nov. 27, 2020), https://www.nytimes.com/2020/11/27/health/covid-hospitals-overload.html.

that of the 52% of people whose families skipped or postponed care during the previous three months due to coronavirus, 82% did so because the doctor's office was closed or had limited appointments.[20]

Increased cost-sharing will also harm Medicaid enrollees under the new IFR policy. Research over the last four decades has consistently concluded that the imposition of cost-sharing on low-income populations reduces both necessary and unnecessary care and correlates with increased risk of poor health outcomes.[21] Further, the pandemic increases the harm caused by cost-sharing. The pandemic has significantly increased financial hardship among low-income families and families of color, making it less likely that they will be able to afford to pay additional cost-sharing.[22]

The IFR also permits states to modify their post-eligibility treatment of income (PETI) rules. This could leave enrollees with disabilities who are institutionalized or using a home and community-based services (HCBS) waiver program with less money to meet their basic needs, which could cause significant harm. For example, if states don't allow HCBS waiver enrollees to keep enough money each month to cover their living expenses, they may be forced into institutions.[23] This prospect is particularly frightening during the pandemic, given the disproportionate impact of COVID-19 on people in congregate settings.[24]

Based on the policy evidence and the language of the statute, we recommend CMS eliminate any flexibility for states to cut optional benefits, reduce amount, duration and scope of benefits, otherwise increase utilization controls, or add costs for enrollees.

Coverage Tiers

CMS should also abandon the coverage tiers system implemented in § 433.400(c), in which individuals can be transitioned between coverage groups with significant benefits differences. The requirements to preserve minimum essential coverage or COVID-related coverage do not cure the violation of § 6008(b)(3), which requires preserving such benefits individuals have had. Nor can CMS justify an unlawful and harmful policy

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[20] Liz Hamel et al., Kaiser Fam. Found., *KFF Health Tracking Poll - June 2020* (2020), https://www.kff.org/report-section/kff-health-tracking-poll-june-2020-social-distancing-delayed-health-care-and-a-look-ahead-to-the-2020-election/.

[21] David Machledt & Jane Perkins, Nat'l Health Law Prog., *Medicaid Premiums and Cost Sharing* (2014), https://healthlaw.org/resource/medicaid-premiums-and-cost-sharing/.

[22] Kim Parker et al., *Economic Fallout from COVID-19 Continues to Hit Low-Income Americans the Hardest*, Pew Rsch. Ctr., https://www.pewsocialtrends.org/2020/09/24/economic-fallout-from-covid-19-continues-to-hit-lower-income-americans-the-hardest/.

[23] Richard W. Johnson & Stephan Linder, Urban Institute, *Older Adults Living Expenses and the Adequacy of Income Allowances for Medicaid Home and Community-Based Services* 2 (2016), https://aspe.hhs.gov/system/files/pdf/255426/livingexp.pdf.

[24] Priya Chidambaram et al., Kaiser Fam. Found., *COVID-19 Has Claimed the Lives of 100,000 Long-Term Care Residents and Staff* (2020), https://www.kff.org/policy-watch/covid-19-has-claimed-the-lives-of-100000-long-term-care-residents-and-staff/.

-- the “blended approach” -- based on the fact it also considered an even more unlawful and harmful policy (the “enrollment interpretation”).

Moving individuals to eligibility groups with fewer benefits can cause substantial harm. For example, under the IFR, some individuals enrolled in § 1915(c) home and community based service waivers could be moved to Medicaid expansion coverage, which can come with increased cost sharing requirements and fewer benefits, leading them to not get needed services. At the same time, some of these individuals have likely been found to no longer be eligible for § 1915(c) waiver enrollment because they received inadequate remote functional assessments during the pandemic -- showing the wisdom of § 6008(b)(3) to maintain the “status quo”.[25]

The IFR carves out a specific exception to the tiers system allowing states to transfer Medicaid enrollees (even those in MEC coverage) into Medicare Savings Programs (MSPs), on the theory that the MSP programs will be connected to Medicare and thus a source of MEC. However, this too is prohibited by the statute. Moreover, such transitions would lead to significant benefit losses and cost increases for consumers, who in many cases will no longer qualify for full-scope Medicaid benefits and will be subject to Medicare’s substantial deductibles and coinsurance.[26] Many individuals in MSPs who require COVID-19 treatment will be forced to pay substantial Medicare cost-sharing for COVID-19-related services like hospitalization that would be free or very low cost under Medicaid.[27]

Moreover, CMS’s interpretation is logically inconsistent. CMS partially recognizes that § 6008(b)(3) extends to maintaining services by requiring the maintenance of minimum essential coverage and COVID-related coverage, while in the same breath insisting the statute does not extend to maintaining services by generally permitting moving individuals to groups with less benefits and permitting cuts to optional benefits.

We are also concerned that states will need to spend significant effort implementing these changes to their eligibility systems. This effort would be far better spent doing other work, such as bolstering their ex parte renewal processes, updating addresses to better prepare for conducting redeterminations at the end of the public health emergency, and focusing on vaccine distribution—which the Trump administration has

[25] David Machledt and Elizabeth Edwards, Nat’l Health Law Prog., *Home-Based Care Under COVID-19: A Do No Harm Approach to Assessing Needs* (2020), https://healthlaw.org/home-based-care-under-covid-19-a-do-no-harm-approach-to-assessing-needs/.
[26] Medicaid & CHIP Payment & Access Comm’n, Medicare Savings Programs, https://www.macpac.gov/subtopic/medicare-savings-programs/ (last visited Dec. 2, 2020).
[27] *See* Juliette Cubanski and Meredith Freed, Kaiser Fam. Found., *FAQs on Medicare Coverage and Costs Related to COVID-19 Testing and Treatment* (2020), https://www.kff.org/coronavirus-covid-19/issue-brief/faqs-on-medicare-coverage-and-costs-related-to-covid-19-testing-and-treatment/; Families First Coronavirus Response Act, Pub. L. No. 116-127, § 6008(b)(4), 134 Stat. 178, 209 (2020).

left almost entirely to the states.[28] Moreover, such massive changes to each states' eligibility system will likely generate errors. Even simply turning off all terminations under the continuous coverage requirement has been difficult for some states to implement correctly -- let alone a tier system of significantly more complexity.[29] These errors will cause harm to enrollees who are placed in the wrong category.

General Eligibility Exceptions

In addition to allowing benefits cuts, the IFR authorizes states to terminate coverage for individuals who should be protected under § 6008(b)(3). The various terminations codified under the IFR are inconsistent with the FFCRA and will cause great harm to individuals who lose their health insurance during the pandemic and economic crisis.

There is evidence pointing to worse COVID-19 outcomes for individuals who are uninsured.[30] Uninsurance combined with COVID-19 will also worsen health disparities.[31] Uninsured individuals are often unaware of provider COVID-19 reimbursement funds that might pay for their care, and even those funds may not pay for some complications related to COVID-19.[32] Uninsured individuals may also be correlated with jobs that have increased COVID-19 exposure risks and no sick time benefits.[33] There is ample evidence that having no health insurance means people lack a regular source of care and are less likely to get important health services.[34] This evidence speaks to the direct harm individuals will suffer under the various eligibility reductions authorized by the IFR.

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[28] *See* Jennifer Wagner, Ctr. on Budget and Pol'y Priorities, *States Can Act Now to Keep Medicaid Enrollees Covered When the Public Health Emergency Ends* (2020), https://www.cbpp.org/sites/default/files/atoms/files/12-2-20health.pdf.

[29] *See, e.g.,* René Mollow, California Dpt. of Health Care Services, Remarks to Medicaid & CHIP Payment & Access Comm'n 18-20 (Oct. 29, 2020), https://www.macpac.gov/wp-content/uploads/2019/10/MACPAC-October-2020-Meeting-Transcript.pdf.

[30] Blake Farmer, Nashville Public Radio, *Hospital Bills for Uninsured COVID Patients Are Covered, but No One Tells Them* (Oct. 2020), https://khn.org/news/hospital-bills-for-uninsured-covid-patients-are-covered-but-no-one-tells-them.

[31] Adam Gaffney et al., *18.2 Million Individuals at Increased Risk of Severe COVID-19 Illness Are Un- or Underinsured*, 35 J GEN. INTERNAL MED. 2487 (2020), https://link.springer.com/article/10.1007%2Fs11606-020-05899-8; Chris Sloan et al., Avalere, *COVID-19 Projected to Worsen Racial Disparities in Health Coverage* (Sept. 2020), https://avalere.com/press-releases/covid-19-projected-to-worsen-racial-disparities-in-health-coverage.

[32] *Id*.; Julie Appleby, Kaiser Health News, *Trump's COVID Program for Uninsured People: It Exists, but Falls Short* (Oct. 2020), https://khn.org/news/fact-check-president-trump-executive-order-covid-program-for-uninsured-people-falls-short; Karyn Schwartz and Jennifer Tolbert, Kaiser Family Foundation, *Limitations of the Program for Uninsured COVID-19 Patients Raise Concerns* (Oct. 2020), https://www.kff.org/policy-watch/limitations-of-the-program-for-uninsured-covid-19-patients-raise-concerns.

[33] Jennifer Tolbert, Kaiser Family Foundation, *What Issues Will Uninsured People Face with Testing and Treatment for COVID-19?* (Mar. 2020), https://www.kff.org/coronavirus-covid-19/fact-sheet/what-issues-will-uninsured-people-face-with-testing-and-treatment-for-covid-19.

[34] *Id*.

For example, under Medicaid's Immigrant Children's Health Improvement Act (ICHIA) option, states can cover lawfully present children and pregnant women without a 5-year wait. Some 35 states elect the ICHIA option for children, and 25 states do so for pregnant women.[35] However, once these children turn 21 and these women finish their 60-day postpartum period, the IFR requires states to terminate their eligibility (other than limited emergency Medicaid condition coverage). Essentially, CMS is, without any clear basis, prioritizing the § 1903(v) payment exclusion over the specific FFCRA MOE requirement despite interpreting the MOE to trump other eligibility and payment exclusions. Congress knows eligibility categories and wrote nothing into the FFCRA to single out this group for exclusion. Indeed, the entire purpose of the MOE is to preserve coverage during this highly and increasing contagious pandemic, along with federal funding for enrollees who may not otherwise be eligible or "matchable" under the Medicaid Act. CMS's interpretation is also overly broad in that it applies to individuals who are lawfully residing, while the § 1903(v) definition includes individuals residing under color of law.

Furthermore, the § 1903(v)(4) definitions restricting coverage to 60 days of post-partum coverage for pregnancy and by age for children were written to mirror the coverage categories for citizens. It would make no sense for CMS to conclude that the FFCRA allows changing the underlying "definitions" for eligible women and children citizens, but not the attempt to mirror those definitions via § 1903(v)(4). Therefore, CMS should not allow disenrollment of any individuals reaching their post-partum limit or aging out.

Meanwhile, carving out these immigrants from comprehensive coverage will cause substantial harm, particularly during the pandemic. Immigrant communities have been disproportionately affected by COVID-19.[36] Depending on their state, COVID-19 testing and treatment may not be covered under emergency Medicaid.[37] Post-partum depression can begin up to a year after delivery.[38] The risk of post-partum disorders is likely increased during the pandemic.[39] Furthermore, individuals will not have coverage for the management of chronic conditions like asthma, diabetes, and high blood pressure. This will reduce access to care, which worsens health outcomes.[40] In many

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[35] Kaiser Fam. Found., Medicaid/CHIP Coverage of Lawfully Residing Immigrant Children and Pregnant Women, https://www.kff.org/health-reform/state-indicator/medicaid-chip-coverage-of-lawfully-residing-immigrant-children-and-pregnant-women/ (last visited Dec. 3, 2020).

[36] Ctrs. for Disease Control and Prevention, Coronavirus Disease 2019 (COVID-19): Specific Groups (Refugees & Migrants) (last updated Oct. 22, 2020), https://www.cdc.gov/coronavirus/2019-ncov/php/rim-considerations.html.

[37] Kaiser Fam. Found., Medicaid Emergency Authority Tracker: Approved State Actions to Address COVID (last updated Nov. 30, 2020), https://www.kff.org/medicaid/issue-brief/medicaid-emergency-authority-tracker-approved-state-actions-to-address-covid-19/.

[38] Department of Health and Human Services Office on Women's Health, *Q+A Postpartum Depression,* https://www.womenshealth.gov/files/documents/fact-sheet-postpartum-depression.pdf.

[39] Pooja Lakshmin, New York Times, *Experts Fear Increase in Postpartum Mood and Anxiety Disorders* (May 27, 2020), https://www.nytimes.com/2020/05/27/parenting/coronavirus-postpartum-depression-anxiety.html.

[40] Benjamin Sommers et al., *Health Insurance Coverage and Health -- What the Recent Evidence Tells Us,* 337 NEW. ENG. J MED. 586 (2017).

cases, reduced control of chronic conditions will also increase the risk of death from COVID-19.[41]

As permitted by the statute, the IFR allows states to effectuate a "voluntary termination" of individuals who wish to drop their coverage. The IFR also adds a policy allowing "voluntary transitions" to a different eligibility group, even if this would otherwise violate the tiering policy created by the IFR. However, without clear and prescriptive protections, these policies may lead to abuses. CMS should include protections to ensure active and informed consent. For example, CMS should clarify that the failure of a consumer to respond to a contact should never constitute a voluntary termination or transition.

CMS newly interprets the statute to allow states to terminate individuals who have not responded to requests to verify residency if the Public Assistance Reporting Information System (PARIS) shows the individual as eligible in two or more states. However, this policy is not supported by the statute and may lead to many individuals being terminated by the state they currently reside in. Even before the pandemic, many individuals who were eligible for Medicaid lost coverage during redeterminations due to barriers associated with Medicaid mailings.[42] During the PHE, these barriers are exacerbated. Many individuals may be unresponsive due to COVID-related health problems or caretaking responsibilities. In addition, the COVID related economic downturn has left many individuals with housing insecurity and spurred displacement and travel restrictions that may impede enrollees' ability to respond.[43] Already, state Medicaid agencies are seeing an increase in returned mail due to the pandemic.[44] At the same time, the U.S. postal service has a record volume of mail and reduced staffing due to COVID-19 infections, leading to historic backlogs of mail.[45] Acknowledging these exceptional circumstances arising from the pandemic, Congress enacted the continuous coverage provision at § 6008(b)(3). Instead of permitting terminations for nonresponsiveness, CMS should require states to communicate with each other until one state is able to confirm residence.

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[41] *See, e.g.,* Lihua Zhu et al., *Association of Blood Glucose Control and Outcomes in Patients with COVID-19 and Pre-existing Type 2 Diabetes,* 31 CELL METABOLISM 1068 (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7252168/pdf/main.pdf.

[42] Samantha Artiga and Olivia Pham, Kaiser Fam. Found., *Recent Medicaid/CHIP Enrollment Declines and Barriers to Maintaining Coverage* (2020), http://files.kff.org/attachment/Issue-Brief-Recent-Medicaid-CHIP-Enrollment-Declines-and-Barriers-to-Maintaining-Coverage.

[43] D'Vera Cohn, Pew Research Ctr., *About a Fifth of U.S. Adults Moved due to COVID-19 or Know Someone Who Did* (2020), https://pewrsr.ch/2Z4sqP3.

[44] Patricia Boozang et al., Manatt Health, *Maintaining Medicaid and CHIP Coverage Amid Postal Delays and Housing Displacements* (2020), https://www.shvs.org/maintaining-medicaid-and-chip-coverage-amid-postal-delays-and-housing-displacements/.

[45] Paul Murphy, CNN, *'Perfect storm' of high package volume, employees out with COVID slowing USPS deliveries before Christmas* (Dec. 23, 2020), https://www.cnn.com/2020/12/23/business/usps-delays-chrismas-trnd/index.html.

Valid Enrollment

Under the IFR (and in conjunction with prior guidance), CMS narrows the definition of "valid enrollment" to exclude some enrollees who should be considered properly enrolled and protected under § 6008(b)(3). First, CMS interprets (b)(3) to allow terminations of individuals enrolled due to agency error at the time of eligibility determination or renewal. While this standard may generally be consistent with the statute, CMS should move the preamble language, requiring a new redetermination review prior to termination, into the regulatory text.

Second, CMS states that individuals eligible by presumptive eligibility are not "validly enrolled" for the purposes of the continuous coverage provision, on the theory that these individuals "have not received a determination of eligibility under the state plan." However, the Medicaid statute consistently describes presumptive eligibility as (for example, under hospital presumptive eligibility) "*determining*, on the basis of preliminary information, whether any individual is eligible for medical assistance *under the State plan* or under a waiver of the plan" (emphasis added).[46] CMS's attempt to distinguish presumptively eligible populations is therefore inconsistent with the statute.

We recommend that CMS adjust its regulation to require continued enrollment for presumptively eligible populations until an individual has been affirmatively determined *ineligible* for Medicaid. This is consistent with the FFCRA's text and intent. It is also consistent with the broader structure of the IFR. The IFR requires continued coverage for individuals who have failed to respond to contacts (at § 433.400(c)(2)(iv)), but allows the state to terminate individuals made eligible by agency error (at § 433.400(b)). In the case of presumptive eligibility, a subsequent and affirmative determination that an individual was ineligible at the time of PE enrollment would be analogous to such agency error.

While protecting states from continued enrollment of individuals who should never have been eligible to enroll, this adjustment would preserve the enrollment of individuals who are struggling to complete full Medicaid applications. For example, many individuals are determined presumptively eligible in hospitals, sometimes during a COVID-19 hospitalization. These individuals may experience significant COVID-19 symptoms during and after hospital discharge that can impede their ability to complete a full application, including symptoms such as fatigue, memory loss, and difficulty concentrating.[47] Many of these same individuals are struggling with economic and housing crises after discharge that understandably have delayed their responses. In fact, CMS's interim policy is potentially counterproductive as states have used

[46] 42 U.S.C. § 1396(a)(47)(B).
[47] Eve Garrigues et al., *Post-Discharge Persistent Symptoms and Health-Related Quality of Life After Hospitalization for COVID-19*, J INFECTION (forthcoming), https://www.journalofinfection.com/action/showPdf?pii=S0163-4453%2820%2930562-4.

presumptive eligibility as an important tool to facilitate coverage in response to COVID-19.[48]

Third, the IFR's authority for states to terminate individuals for fraud or abuse is overbroad. The IFR states that if the state conducts an abuse investigation under 42 C.F.R. § 455.15-16 and finds abuse "attributed to the beneficiary or the beneficiary's representative which was material to the determination of eligibility," the individual is not validly enrolled. However, 42 C.F.R. § 455.16 does not itself necessarily require an individual be disenrolled: it explicitly references state options such as "[s]ending a warning letter...giving notice that continuation of the activity in question will result in further action." CMS should not impose outcomes that supplant or skip the state processes already in place and specified by regulations.

Determinations of Ineligibility

The interim regulation at § 430.400(c)(2)(iv) states that "if a state *determines* that a validly enrolled beneficiary is no longer eligible for Medicaid, including on a procedural basis," the state meets the MOE requirements by "continuing to provide the same Medicaid coverage that the beneficiary would have received absent the *determination* of ineligibility" (emphasis added). This language needs clarification and correction. We note two important considerations.

First, we commend and believe CMS must preserve the requirement that the MOE requirement apply to procedural problems. For example, an individual who is delayed in responding to state outreach or requests for information may be dealing with serious health, economic, or housing problems related to the COVID-19 crisis, and such procedural breakdowns cannot be an excuse to discontinue eligibility in violation of § 6008(b)(3).

Second, however, CMS must correct or clarify the use of the terms "determines" and "determination." The statutory language of § 6008(b)(3) states that any individual enrolled in Medicaid during the emergency period "shall be treated as eligible ... through the end of the month in which such emergency period ends…". A person is either eligible or ineligible for Medicaid. If a state issues a "determination" during the PHE that someone is ineligible for Medicaid, that would be contrary to the statutory requirement to treat them as eligible. CMS should not use the term "determination" to describe any state shadow eligibility reviews that are conducted during the MOE period. No one protected by the MOE can be "determined" ineligible during the PHE. We suggest CMS use a term such as "nonactionable finding of ineligibility" instead of "determination of ineligibility."

[48] Rebecca Landucci et al., Health Affairs Blog, *How States Are Facilitating Medicaid Enrollment During COVID-19—And How They Can Do Even More* (June 17, 2020), https://www.healthaffairs.org/do/10.1377/hblog20200612.887360/full.

Moreover, CMS should make clear that any such nonactionable finding of ineligibility during the public health emergency is not sufficient or even relevant to terminate someone at the end of the PHE. CMS should retract the Dear State Health Official letter issued December 22, 2020. In this regulation and new guidance, HHS should specify that, *after* the PHE ends, individuals must receive a full redetermination based on *current* information (income, household composition, etc.).[49] CMS should also immediately clarify for states that it is impermissible for a state to send a notice to individuals during the PHE indicating that their coverage ends at a future date, as some states have indicated they are doing.[50] First, no state can know the end date for the PHE until it actually expires. Second, no state can know the actual eligibility of an individual until the end of the applicable MOE period (*i.e.*, the end of month in which the PHE ends). Any findings prior to that date are nonactionable findings of eligibility that are immaterial to the *full eligibility review* that must be conducted, *after* the MOE period ends, and *prior* to any actionable determination of eligibility. Such a review must consider all bases of eligibility, and give enrollees at least 30 days to respond to a request for information (for those eligible using modified adjusted gross income).[51]

Third, we also note that states are not permitted to give enrollees more than 90 days from the notice of action to request a fair hearing.[52] Therefore, if states mailed a determination of "ineligibility" more than three months before the continuous coverage requirement ends, an individual would not be able to request a fair hearing based on the notice when their coverage ends -- an outcome clearly inconsistent with due process.

Finally, after the MOE period ends and a subsequent full redetermination of eligibility is conducted, if an individual is found ineligible they are entitled to due process protections, such as a notice of termination that includes the effective date of the action and appeal rights.[53]

In summary, CMS should clarify this regulation and other guidance to specify that states may not make determinations or other actionable findings of eligibility during the MOE period. And, after the MOE period ends, states must use only *current* information to conduct a full eligibility review and, thereafter, observe all due process requirements, prior to any termination. Instead of allowing states to terminate people based on outdated information, CMS should concentrate its efforts on ensuring that states provide full redeterminations *and* phase those reviews in slowly over the course of the full year after the PHE ends.

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[49] *See e.g.,* 42 C.F.R. § 435.603(h)(2).
[50] *See, e.g.,* Texas Health and Human Services, *Stakeholder Update: COVID-19, Medicaid and CHIP Services* 12 (2020), https://hhs.texas.gov/sites/default/files/documents/services/health/coronavirus-covid-19/mcs-covid-19-info-handout-aug-6-2020.pdf.
[51] 42 C.F.R. § 435.916
[52] 42 C.F.R. § 431.221(d)
[53] *See e.g.,* 42 C.F.R. §§ 435.917(b)(2), 431.210

III. FFCRA Vaccination Coverage Requirement

As of December 29, 2020, more than 334,000 people in the United States have died as a result of COVID-19, with over 19 million confirmed cases.[54] Public health experts agree that widespread use of a safe and effective preventive vaccine will be essential to curb this deadly pandemic. Congress recognized the vital importance of coverage and access to COVID-19 vaccines when it enacted the FFCRA. Congress provided that state Medicaid programs receive enhanced federal funding if they cover approved COVID-19 vaccines, and provide access without cost sharing, during the period of the public health emergency.[55]

However, as the deadly pandemic rages and the vaccines are finally arriving, CMS is inexplicably misinterpreting the statute in a way that may reduce access to COVID-19 vaccines. CMS introduces a new interpretation of FFCRA that would allow states to obtain enhanced stimulus dollars even if they do not cover COVID-19 vaccination in Medicaid limited benefit programs.[56] Medicaid limited benefit programs include the Breast and Cervical Cancer Treatment Program (BCCTP), the program for people with tuberculosis, family planning programs, as well as some programs provided under § 1115 waiver authority.[57]

The FFCRA, at § 6008(b)(4), makes no distinction between full and limited benefit Medicaid categories. It also specifically applies vaccination requirements to waiver programs. The obvious intent of the provision was to ensure widespread access to COVID-19 vaccination. Congress's statute is clear. CMS should not invent an ambiguity and then interpret it contrary to the statute's overriding intent. Congress is well familiar with limited scope benefits categories and would have carved out exceptions to § 6008(b)(4) if it wanted to carve out such exceptions.

Barring payment for COVID-19 vaccines or slowing access by disrupting streamlined state coverage through Medicaid for all Medicaid enrollees would hamper efforts to combat the pandemic. Tens of thousands of individuals who rely on Medicaid limited benefit programs would be harmed. For example, Medicaid provides health care for persons with breast and cervical cancer who are not otherwise covered under creditable coverage.[58] Nearly 44,000 people are enrolled in the BCCTP program.[59] The existence of federal reimbursement funds may not be enough to promote vaccination and convince individuals that vaccination will be covered; this has been a problem in

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[54] Johns Hopkins University of Medicine, Coronavirus Resource Center, United States, https://coronavirus.jhu.edu/region/united-states (last visited Dec. 29, 2020).
[55] Families First Coronavirus Response Act, Pub. Law 116-127, § 6008 (Mar. 18, 2020), https://www.congress.gov/116/plaws/publ127/PLAW-116publ127.pdf.
[56] 85 Fed. Reg. 71149-71150, 71198, *proposed as* 42 C.F.R. § 433.400(c)(2)(ii).
[57] See 42 U.S.C. § 1396a(aa) (Breast and Cervical Cancer Program); 42 U.S.C. § 1396a(z) (Tuberculosis); 42 U.S.C. § 1396a(ii) (Family Planning); 42 U.S.C. § 1315 (Section 1115 demonstration projects).
[58] 42 U.S.C. § 1396a(aa).
[59] GAO, *Federal Programs Provide Screening and Treatment for Breast and Cervical Cancer* 37 (2020), https://www.gao.gov/assets/720/710372.pdf.

COVID-19 testing and treatment.[60] Most importantly, there is clear evidence that Medicaid enrollment is positively correlated with vaccination. For example, children enrolled in Medicaid are much more likely to be vaccinated than uninsured children, despite the existence of Vaccines for Children (VFC) funding which *should* be reimbursing vaccination for uninsured children.[61] As an illustrative example, consider DTaP (3-dose) vaccination: although Medicaid children lag slightly behind privately insured children (92.5% to 95.9%), both groups are far ahead of uninsured children (80.2%).[62]

As of October 2020, 44 states had a total of 57 approved § 1115 Medicaid waivers.[63] CMS does not provide any explanation about how it would determine which of these waiver programs would be subject to the IFR limits on vaccine coverage. Presumably, it would require a state-by-state analysis of the terms and conditions of limited benefit waiver programs, such those providing family planning services, to determine if they cover services which CMS deems sufficiently related to vaccines.[64] However, we can only speculate. What is clear is that women enroll in family planning waivers and other waivers in significant numbers and will bear the brunt of COVID-19 vaccine access restrictions.

This policy is inconsistent with the FFCRA statutory language and intent, relies on misreading of the Medicaid statute, and is harmful as a matter of health policy. It should be withdrawn.

IV. Section 1332 Transparency Requirements

Under the IFR, CMS also proposes to allow the "modification" of public notice, comment, and hearing requirements for 1332 waiver requests, as well as post-award

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[60] Blake Farmer, Nashville Public Radio, *Hospital Bills for Uninsured COVID Patients Are Covered, but No One Tells Them* (Oct. 2020), https://khn.org/news/hospital-bills-for-uninsured-covid-patients-are-covered-but-no-one-tells-them; Julie Appleby, Kaiser Health News, *Trump's COVID Program for Uninsured People: It Exists, but Falls Short* (Oct. 2020), https://khn.org/news/fact-check-president-trump-executive-order-covid-program-for-uninsured-people-falls-short; Karyn Schwartz and Jennifer Tolbert, Kaiser Family Foundation, *Limitations of the Program for Uninsured COVID-19 Patients Raise Concerns* (Oct. 2020), https://www.kff.org/policy-watch/limitations-of-the-program-for-uninsured-covid-19-patients-raise-concerns.

[61] Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report, *Vaccination Coverage Among Children Aged 19-35 Months – United States, 2016* (Nov. 3, 2017), https://www.cdc.gov/mmwr/volumes/66/wr/mm6643a3.htm.

[62] *Id*. at Table 2.

[63] Madeline Guth, et al., Kaiser Fam. Found., *The Landscape of Medicaid Demonstration Waivers Ahead of the 2020 Election* (2020), https://www.kff.org/medicaid/issue-brief/the-landscape-of-medicaid-demonstration-waivers-ahead-of-the-2020-election/.

[64] *E.g.*, inpatient hospital services (42 C.F.R. § 440.10), outpatient hospital services (42 C.F.R. § 440.20(a)), rural health clinic services (42 C.F.R. § 440.20(b)), Federally Qualified Health Centers (FQHCs), and physicians' services (42 C.F.R. § 440.50), preventive services (42 C.F.R. § 440.130(c)), other licensed practitioners (42 C.F.R. § 440.60), or clinic services (42 C.F.R. § 440.90). *See also* CMS, *Coverage and Reimbursement of COVID-19 Vaccines, Vaccine Administration, and Cost Sharing under Medicaid, the Children's Health Insurance Program, and Basic Health Program* (Nov. 23, 2020), https://www.medicaid.gov/state-resource-center/downloads/covid-19-vaccine-toolkit.pdf.

public hearings. These exceptions conflict with 1332 statutory requirements, and are overbroad and unnecessary.

The Affordable Care Act requires public notice, comment, and hearings for § 1332 waivers, as well as public notice and comment opportunities after waiver approval. CMS's interim regulations conflict with the statute in that, through "modification," they might allow the *elimination* of required transparency provisions. The IFR would also allow public notice and comment periods to be effectuated *after* the state files the application (in the case of state comment periods) or CMS conducts federal review (in the case of federal comment period). This will result in state proposals and CMS approvals that have no meaningful stakeholder input, violating the statute and congressional intent.

This proposal is also overbroad. CMS suggests that there could be situations where there would be an urgent need to implement a policy responsive to COVID-19. However, given the diffuse impacts of COVID-19, CMS's IFR could open the door to states modifying transparency for essentially *any* 1332 waiver that occurs during the COVID-19 PHE. As CMS notes, almost all of the 1332 waivers granted thus far concern reinsurance programs, which may reduce premiums over the long term. While the regulation includes some language requiring the modifications to relate to "emergent" situations, that language seems meaningless if, as CMS suggests, a waiver like a statewide reinsurance program qualifies as emergent. Moreover, this policy should not apply to extensions. A waiver extension is by definition not related to COVID-19, since the current waivers were designed prior to the known existence of the virus.

We also do not believe that this proposal is necessary. In addition to being required by statute, the transparency process creates a minimal delay in exchange for substantial benefit. For example, while a state reinsurance program might create *long-term* slowing of premium growth, which in turn might marginally influence enrollment, this is an attenuated chain. Delaying for notice and comment will not materially change the impact of the policy on the COVID emergency. As CMS has previously noted, the public notice and comment process on 1332 waivers "promotes transparency, facilitates public involvement and input, and encourages sound decision-making at all levels of government".[65] This process is essential to ensure that consumers have input into proposed waivers.

Conclusion

NHeLP recommends that the Department of Health and Human Services not finalize provisions of the IFR interpreting the FFCRA MOE, the FFCRA vaccination coverage requirement, and the § 1332 transparency process because they are inconsistent with

[65] 76 Fed. Reg. 13556 (Mar. 14, 2011).

statutory requirements and would result in serious harms to exchange and Medicaid enrollees.

We have included numerous citations to supporting research, including direct links to the research. We direct HHS to each of the studies we have cited and made available through active links, and we request that the full text of each of the studies cited, along with the full text of our comment, be considered part of the formal administrative record for purposes of the Administrative Procedure Act. If HHS is not planning to consider these citations part of the record as we have requested here, we ask that you notify us and provide us an opportunity to submit copies of the studies into the record.

We appreciate your consideration of our comments. If you have questions about these comments, please contact me.

Sincerely,

Leonardo Cuello
Director, Health Policy
cuello@healthlaw.org