
January 4, 2021

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Baltimore, MD 21244-8013

Attention: CMS-9912-IFC

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

We are writing on behalf of the HIV Health Care Access Working Group (HHCAWG) – a coalition of over 100 national and community-based HIV service organizations representing HIV medical providers, public health professionals, advocates, and people living with HIV who are all committed to ensuring access to critical HIV and hepatitis C-related healthcare and support services. We appreciate the opportunity to provide comments on this interim final rule with request for comments "Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency".

The Families First Coronavirus Response Act (FFCRA), 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 maintenance of effort (MOE) protections. These protections help ensure individuals are able to get and stay covered during the crisis and receive needed services. The FFCRA includes an explicit requirement to preserve enrollee's existing benefits – both their enrollment in Medicaid overall, and the services for which they have been eligible. At a time of such turmoil, Congress chose to protect enrollees and ensure access to services by maintaining the "status quo."

We are writing to express our deep concern about several provisions of this Interim Final Rule (IFR). In a reversal of CMS's stated policy from March to October 2020, this IFR would now allow states to impose numerous types of coverage restrictions for individuals who are enrolled in Medicaid, including reduced benefits; reduced amount, duration, and scope of services; increased cost-sharing; and reduced post-eligibility income. The IFR will also result in terminations for some individuals who should not be terminated. We oppose these revisions to the MOE, which are inconsistent with the FFCRA and will result in harm for Medicaid enrollees. We also oppose allowing states to circumvent required transparency procedures for 1332 waivers and receive enhanced funding despite refusing to cover COVID-19 vaccination for some Medicaid enrollees. We recommend that CMS withdraw these provisions.

**Improper Use of an Interim Final Rule**

At the outset, we note that the use of an IFR to issue many of the provisions contained in the rule is improper, and urge CMS to withdraw these proposals. In particular, we do not believe "good cause" to waive advance notice-and-comment procedures exists concerning the changes to State Innovation Waivers under Section 1332 of the Affordable Care Act (ACA). We also do not believe good cause exists regarding the new interpretation of Section 6008(b) of the FFCRA.

Under Section 553(b)(B) of the Administrative Procedure Act (APA), use of an IFR is permitted only when an agency for good cause, finds that compliance with the notice-and-comment procedures of the APA would be "impracticable, unnecessary, or contrary to the public interest." Good cause applies in a few situations: where an IFR seeks to address an emergency, where notice-and-comment would subvert the statutory scheme of the applicable statute, and where Congress intends to waive a notice and comment requirement.[1] However, the provisions in the IFR addressing 1332 waiver application procedures, and the provisions re-interpreting section 6008(b) of the FFCRA do not properly fit into any of these categories.

CMS asserts that 1332 waivers are a critical tool for states to ensure the health of their residents.[2] As a result, it has waived many of the procedures typically required when states apply for 1332 waivers. However, use of an IFR here does not meet the good cause requirement. No state is currently seeking an Innovation Waiver, nor has CMS identified any state that has been deterred from doing so due to the public notice and comment procedure for application. Consequently, an emergency justification for the use of an IFR is unwarranted for the changes to transparency and application procedures for 1332 waivers.

Moreover, use of an IFR in interpreting Section 6008(b) of the FFCRA is also inappropriate. Despite seeking to use an emergency justification for the use of an IFR here, CMS has already interpreted Section 6008 in an extensive FAQ issued in April 2020.[3] CMS does not explain why, if it felt that 6008 needed re-interpretation, it could not do so via a subsequent FAQ instead of improperly utilizing an IFR. No additional emergency situations have arisen since the FAQs were released that would justify re-interpreting Section 6008 through an IFR. Indeed, the statutory scheme from April has remained the same with little complaints from commenters that would warrant using an IFR to better carry out FFCRA's statutory mandates. Finally, Congress has not indicated it sought further clarification or regulation since the FAQs were already issued back in April interpreting Section 6008(b) FFCRA.

**Reinterpretation of FFCRA § 6008**

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[1] Jared P. Cole, *The Good Cause Exception to Notice and Comment Rulemaking: Judicial Review of Agency Action*, Congressional Research Service (January 29, 2016), available at: https://fas.org/sgp/crs/misc/R44356.pdf .
[2] CMS-9912-IFC at 136.
[3] Families First Coronavirus Response Act – Increased FMAP FAQs, available at: https://www.medicaid.gov/state-resource-center/downloads/covid-19-section-6008-faqs.pdf

The Medicaid program is a critical source of health coverage for life-saving care for people living with HIV. Forty-two percent of adults living with HIV are covered by Medicaid, compared to just 13% of the general population.[4] These individuals count on the Medicaid program for the health care and treatment that keeps them healthy. Ensuring uninterrupted access to effective HIV care and treatment is important to the health of people living with HIV and to public health.[5] When HIV is effectively managed, the risk of transmitting the virus drops to zero.[6]

Protecting the most vulnerable and least economically secure enrolled in Medicaid during the COVID-19 is crucial to ensure that these beneficiaries can access life-saving health care. The plain text of Section 6008(b)(3) of the FFRCA recognized this importance. However, CMS ignores this importance through its "blended approach." This blended approach permits states to transfer Medicaid beneficiaries into a "somewhat different" set of benefits that may include cost sharing burdens for certain services that the beneficiary previously did not have to endure. Thus, CMS's new interpretation renders Section 6008(b)(3) meaningless.

We urge CMS to abandon this blended approach and ensure that states may not increase cost sharing, add new utilization management requirements, or reduce the amount and scope of services provided to enrollees.

*Reduction of Benefits and Additional Burdens*

This IFR deviates from the robust statutory protections Section 6008(b)(3) affords to Medicaid beneficiaries. Indeed, CMS strays from its initial straightforward interpretation of the statute back in April with a new "blended approach." This blended approach expressly permits states to enroll certain beneficiaries into a "somewhat different" set of benefits through the state's ABP, and may include cost sharing for certain services.[7] Specifically, CMS encourages states to allow a child on minimum essential coverage who reaches age 19 to be transferred to a new Adult Group Plan that also has minimum essential coverage. CMS notes this transfer is permissible despite the somewhat different set of benefits and additional cost sharing burden. But CMS fails to realize that this transfer is far more consequential than just a new and different set of benefits for the hypothetical teenager.

Taking CMS' example to it its logical conclusion reveals CMS' glaring interpretative error. For instance, Indiana's Medicaid expansion through its 1115 waiver has an enforceable premium and work requirement that this newly 19-year old beneficiary previously did not have to pay.[8] However, the plain language of the FFRCA requires "an individual who is enrolled for benefits

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[4] *Medicaid and HIV*, KAISER FAMILY FOUND. (Oct. 1, 2019), https://www.kff.org/hivaids/fact-sheet/medicaid-and-hiv/.

[5] Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. Available at http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL. pdf.

[6] Cohen, MS., et al. Antiretroviral Therapy for the Prevention of HIV-1 Transmission. N Engl J Med 2016; 375:830-839. September 1, 2016.

[7] CMS-9912-IFC at 86-87.

[8] Healthy Indiana Plan, Medicaid.gov, (Jan 30, 2015), available at: https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/81641

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."[9] In other words, the plain language requires that states ensure beneficiaries maintain the "benefits" they enjoyed prior to the Public Health Crisis.

However, CMS' blended approach flouts the statutory mandate by allowing states (Indiana or Kentucky for example, whose waivers have additional requirements) to increase the financial and work burdens on individuals. These increased cost and work burdens makes accessing care and maintaining the same costs much more difficult for low income residents who cannot afford additional cost sharing during a pandemic and looming economic crisis. Indeed, the statute's mandate that residents maintain the same benefits will be compromised if states are free to add cost burdens that preclude low income residents from maintaining benefits they previously did not endure. In other words, residents will lack the same benefits during the public health crisis because they are less likely to access care if states are free to increase unaffordable cost burdens. Unfortunately, CMS' blended approach expressly permits this cost or work burden increase, which directly contradicts the statute's requirement that residents maintain access to the same set of benefits.

*Prior Authorizations*

The IFR would also allow states to impose new prior authorizations and other utilization management requirements. This is particularly concerning for people living with HIV as well as people at risk of HIV taking pre-exposure prophylaxis, as consistent and timely access to medication is crucial to maintaining both individual and public health. Prior authorization already presents problems for people living with HIV, their providers, and public health. Unnecessary delays can cause treatment disruptions, viral resistance, and lack of viral suppression. Furthermore, prior authorizations create a labyrinth of hurdles for providers, forcing them to spend hours of extra office work completing paperwork that on balance, does not improve patient care.[10] Particularly as our nation's health care providers are already stretched thin during the COVID-19 pandemic, allowing Medicaid to impose this bureaucratic requirement is placing unnecessary burdens on an already-strained system

## 1332 Waiver Changes

Ensuring states are equipped with adequate means to respond to the challenges associated with the COVID-19 crisis is critical. In this IFR, CMS asserts that one of the ways to protect consumers from the effects of the crisis is to remove administrative barriers normally required of states when they apply for State Innovation Waivers. CMS, however, gives no indication of the types of waivers that would be effective in combatting COVID-19.

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[9] 42 U.S.C. § 1396d.

[10] American Academy of HIV Medicine, Prior Authorization, https://aahivm.org/wpcontent/uploads/2016/12/AAHIVM-policy-one-pager-Prior-Authorization-FINAL.pdf.

State Innovation Waivers have been typically used for implementing reinsurance programs that lower premiums for consumers. Indeed, CMS even notes that 14 of the 15 waivers currently in use have been to establish reinsurance programs that stabilize health care marketplaces.[11] However, CMS fails to give any explanation as to how these waivers would help in fighting COVID-19. Specifically, CMS gives no indication as to how the prospect of lower premiums through Innovation Waivers would help consumers.

In fact, because of the COVID-19 crisis, U.S. health insurers are reporting unprecedented profits.[12] Indeed, since the pandemic began, insurers have been reaping millions of dollars in rebates and avoiding the de-stabilizing market features that reinsurance programs are designed to combat.[13] As a result, CMS's decision to fast-track Innovation Waivers for a non-existent problem simply has no policy basis, and removes a critical opportunity for public comment. Consequently, we urge CMS to withdraw this provision of the IFR.

**Scope of Requirement Under Section 2713 of the Public Health Service Act – Related Items and Services**

HHCAWG supports finalizing this provision of the IFR. CMS clarifies here that under section 2713 of the Affordable Care Act, required no-cost coverage of preventive services recommended by the USPSTF and/or ACIP includes coverage of "items and services that are integral to the furnishing of the recommended preventive service, regardless of whether the item of service is billed separately."[14] We wholeheartedly agree that the Affordable Care Act's no-cost preventive service coverage mandate must extend to not only the service specified by the USPSTF and/or ACIP, but any ancillary services that are medically required in conjunction with the recommended service. HHCAWG notes that we are concerned about the scope of this requirement as insurers prepare to implement the USPSTF's Grade A recommendation for pre-exposure prophylaxis (PrEP) finalized in June 2019.[15] PrEP is a once-daily anti-retroviral medication that when taken regularly prevents acquisition of HIV.[16]

According to the CDC PrEP Guideline, there are a number of services in addition to the medication itself that are integral to the PrEP intervention. To ensure meaningful access to PrEP, and to avoid a "bait and switch" for consumers seeking a prescription for PrEP with the understanding that it is available without cost sharing, these services must be covered without

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[11] Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, 85 FR 71142, 71177 (November 6, 2020).
[12] Reed Abelson, *Major U.S. Health Insurers Report Big Profits, Benefitting From the Pandemic*, The New York Times (Aug. 5, 2020), available at: https://www.nytimes.com/2020/08/05/health/covid-insurance-profits.html
[13] *Id.*
[14] Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, 85 FR 71142, 71174 (November 6, 2020)
[15] USPSTF Final Grade A Recommendation for PrEP (June 2019), available at https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis.
[16] Pacific AIDS Education & Training Center, PrEP Efficacy Trial Results, available at http://paetc.org/wp-content/uploads/2018/02/PAETC_PrEPEfficacy.pdf. A recent study examining PrEP persistence among those on employer-sponsored insurance found that of those taking PrEP remained on it for an average of 14.5 months. Huang Y-L A et al., Persistence with HIV preexposure prophylaxis in the United States, 2012-2016. Conference on Retroviruses and Opportunistic Infections, Seattle, abstract 106, 2019.

cost sharing. Existing sub-regulatory guidance on other USPSTF recommended services referenced in this IFR have similarly required coverage of ancillary services that are inextricable from the underlying intervention (for example, CMS stated that a polyp removal that occurs in the course of a colonoscopy that meets USPSTF criteria must also be covered without cost sharing as polyp removal is an integral part of a colonoscopy).[17] The chart below shows the services that are currently inextricably linked to PrEP and should be covered without cost sharing. In considering the scope of § 2713, HHCAWG re-iterates our call for specific guidance to plans on PrEP coverage that explicitly includes ancillary services described in the CDC PrEP Guideline, which is updated regularly in line with best clinical practice.

| **PrEP Clinic/Lab Service at Regular Intervals** |
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| Clinical visit (w/ primary care, infectious disease specialist, pharmacist, or public health clinic) |
| HIV tests |
| Pregnancy testing of all cisgender women and transgender men with reproductive potential |
| Hepatitis B test |
| Medication adverse event assessment, adherence counseling, and behavioral risk reduction support |
| Bacterial STI tests, including three-site extragenital testing for chlamydia and gonorrhea |
| Renal functioning test |

Thank you for your consideration of these comments. If you have further questions, please reach out to HHCAWG co-chair Phil Waters at pwaters@law.harvard.edu with the Center of Health Law and Policy Innovation, Rachel Klein and rklein@taimail.org with The AIDS Institute, or Aisha Davis at adavis@aidschigaco.org with AIDS Foundation of Chicago if we can be of assistance.

Respectfully submitted by:

ADAP Advocacy Association
ADAP Educational Initiative
AIDS Alabama AIDS Action Baltimore
AIDS Alliance for Women, Infants, Children, Youth & Families
AIDS Foundation of Chicago
AIDS Research Consortium of Atlanta
AIDS United
American Academy of HIV Medicine
APLA Health
Bailey House, Inc.

[17] Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, 85 FR 71142, 71174 (November 6, 2020)

Black AIDS Institute
Center for Health Law and Policy Innovation
Communities Advocating Emergency AIDS Relief (CAEAR)
Community Access National Network (CANN)
Food Is Medicine Coalition
Georgia AIDS Coalition
Harm Reduction Coalition
HealthHIV
HIV Medicine Association
HIV+Hepatitis Policy Institute
Housing Works
Lambda Legal
Legal Council for Health Justice
Michigan Positive Action Coalition
Minnesota AIDS Project
National Alliance of State and Territorial AIDS Directors
National Latino AIDS Action Network
National Working Positive Coalition
NMAC Positive Health Solutions of the University of Illinois
Positive Women's Network – USA
Prevention Access Campaign
San Francisco AIDS Foundation
SisterLove
Southern AIDS Coalition
The AIDS Institute
Thrive Alabama
Treatment Access Expansion Project
Treatment Action Group
Vivent Health