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Director, Division of Information Collections and Regulatory Impacts
Office of Strategic Operations and Regulatory Affairs
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Room C4-26-05
Baltimore, Maryland 21244-1850

Submitted electronically via email

RE: (CMS-10341) Section 1115 Demonstration Projects Regulations

Dear Director Parham:

On behalf of Families USA, thank you for the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS') intention to collect information from states under the Paperwork Reduction Act of 1995 (PRA).

Families USA is a leading national, non-partisan voice for health care consumers, dedicated to achieving high-quality, affordable health care and improved health for all. Families USA greatly appreciates the opportunity to comment here, as the information CMS proposes to collect is of high importance to CMS and to the populations served by the Medicaid program.

Under the Paperwork Reduction Act of 1995 (PRA),¹ federal agencies are asked to periodically publish notice in the Federal Register concerning collection of information ("PRA notice")—in this case, proposing to extend collection activities as they relate to state Section 1115 Medicaid demonstration projects that test new approaches for delivering Medicaid services—allowing a renewed opportunity for public comment on the information being collected.

We are supportive of CMS in issuing this PRA notice as it serves as a recommitment to CMS' obligations under the Social Security Act to keep the development, implementation, and evaluation of Section 1115 Medicaid demonstration projects transparent and open to the public. While many aspects of the information CMS proposes to collect under this PRA notice are important, we focus our comments on proposed information collection in connection to public engagement in the demonstration process. It is important for CMS to ensure states have sought public input and thoughtfully considered and responded to feedback at all stages of the process, including prior to submitting, modifying or extending any demonstration.

I. Transparency in the Section 1115 demonstration process is important, and the Social Security Act requires states to provide clear opportunities for the public to review and comment on any proposed Medicaid demonstration.

Medicaid demonstrations allow states flexibility to test new approaches for providing coverage and delivering Medicaid services. Section 1115 of the Social Security Act provides the Secretary of Health and Human Services (HHS) with broad authority to waive certain federal Medicaid requirements to allow states to pursue a Medicaid demonstration,² so long as the proposed demonstration is likely to "promote the objectives" of the Medicaid program,³ and remains "budget neutral" to the federal government.⁴ Considering the ubiquity of Section 1115 waivers (47 state Medicaid programs operate with at least one active waiver and some states have multiple waivers)⁵ and given the increasingly broad scope of waivers that give states the flexibility to strengthen delivery systems or restructure financing and other program elements,⁶ it is critical that the array of stakeholders impacted—including Medicaid-eligible populations, health care

providers who treat Medicaid patients, and private health plans that organize Medicaid care delivery—have a meaningful way to provide input into the waiver process.

Since 1994, HHS regulations have included processes for soliciting public input at both the state and federal levels prior to finalization of Section 1115 waivers.^{7,8} In response to a series of reports from the Government Accountability Office (GAO) outlining numerous instances of important policy changes to state Medicaid programs being made out of the public's eye,⁹ Congress pushed HHS to ensure more robust opportunities for the public to learn about and provide feedback on proposed Medicaid demonstrations. Since 2010, Congress has required HHS to have in place a process for public notice and comment at both the state and CMS levels that is "sufficient to ensure a meaningful level of public input."¹⁰ Per the Social Security Act, such public processes must be in place where there are applications for or extensions of any 1115 demonstration project impacting Medicaid or CHIP "eligibility, enrollment, benefits, cost-sharing, or financing."¹¹

Related to the present PRA notice, CMS' implementing rules require states to:

- Provide clear opportunities for public comment before submitting an 1115 waiver request or extension to CMS (including a minimum 30-day public notice and comment period along with two or more public hearings and a website maintained with full information about the state's proposed or extended demonstration).¹²
- Show, upon submission of 1115 waiver application or extension to CMS, that there was a meaningful public comment period and that the state has taken the comments into consideration when preparing their submission.¹³
- Perform periodic reviews and an evaluation of their demonstration, soliciting public comments on the progress of the demonstration project.^{14,15}

These statutory and regulatory requirements not only serve to inform interested stakeholders of major proposed changes to the Medicaid program, but also present stakeholders with an opportunity to lend their lived experience and/or technical expertise to the process in a way that ensures state Medicaid officials are better able to meet the goals of the demonstration program as well as the needs of the communities that rely on Medicaid for health insurance. For example, upon hearing feedback from hospital providers that New Mexico's proposed co-payment and cost sharing requirements for Medicaid members would cause increased administrative burdens for healthcare providers (such that any system savings for Medicaid would be offset by increasing costs for providers), the state decided to remove most co-payments from its 2017 final waiver application.¹⁶ In Kentucky, stakeholder feedback to the state's midpoint evaluation of its current substance use disorder (SUD) demonstration in 2021 revealed that primary health care providers needed better training on the elements of the SUD services offered under the demonstration so they could appropriately refer eligible patients to these services.¹⁷ These examples reflect how initial and ongoing feedback are critical to making sure 1115 demonstrations achieve their aims and use the federal flexibility—and dollars—granted to them most effectively.

II. Collection activities proposed under the Section 1115 information collection extension are appropriate and meet the goals of the Paperwork Reduction Act.

The process of soliciting public input into the 1115 waiver process (as outlined above) not only meets requirements under the Social Security Act but also meets the goals of the PRA. The PRA asks Federal agencies to balance several goals in effort to minimize paperwork burdens (to individuals, businesses, contractors and state and local governments), while maximizing the utility of the information collected to "ensure the greatest possible public benefit."¹⁸ Importantly, one stated goal of the PRA is to:

"improve the quality and use of Federal information to strengthen decision-making, accountability, and openness in Government and society"¹⁹

As outlined above, public input at all stages of the process—from state waiver development to implementation to evaluation—improves the quality of information the state has to evaluate and develop demonstration programs. Public input (and the states' obligation to show the federal government it has collected this input) also serves to improve the quality of information the federal government has to make informed decisions about Section 1115 demonstration applications. When states submit a waiver application to CMS, they outline all public comments received and how they

have responded to that feedback in their demonstration; CMS may deny aspects of a state's application for failure to respond to legitimate public concerns. For example, in 2019, CMS denied the portion of Utah's waiver application that asked to waive mandatory Early Periodic Screening, Diagnoses, and Testing (EPSDT) services to individuals between the ages of 19 and 21 enrolled in its Medicaid expansion program, due, in part, to Utah's failure to meaningfully address the strong opposition received from the public on this proposed benefit denial.^{20,21,22}

CMS' ability to effectively review 1115 demonstration applications is greatly enhanced by information collection activities that ensure states engage with the public. Of course, this information collection is not perfect, and public input is not always supported by states in accordance with the law.²³ As concluded by a 2019 GAO report, gaps in transparency and public input "may leave [CMS] and the public without key information to fully understand the potential impact of the changes being proposed, including on beneficiaries and costs."²⁴ To GAO, it is the public input and adherence to the process for collecting that public input that is of paramount importance to the federal government in its decision making with regard to Section 1115 waivers.

A robust public input process supported by state information collection requirements not only addresses gaps outlined by GAO, but meets the PRA's goals of information collection that strengthens "accountability" and "openness in Government and society." For these many reasons, we support this PRA notice and the proposed continued collection of critical information from states as they pursue 1115 demonstrations.

III. This PRA notice serves as an important statement from CMS to reconfirm its commitment to hold states accountable to providing a public comment period in accordance with the law.

We note that CMS has not always held states accountable to providing a public comment period prior to submission to CMS, even when waivers have proposed significant changes to a state's Medicaid program.²⁵ For example, in June 2017, CMS did not enforce state-level public notice and comment procedures before Indiana submitted extensive amendments to its 1115 waiver, including imposing a work reporting requirement as a condition of eligibility.^{26,27} Here, CMS opened the federal comment period while the state comment period was ongoing, meaning comments from the Indiana public were not considered prior to CMS submission. Then, in July 2017, CMS deemed an amendment request from Kentucky as complete,^{28,29} again opening the federal comment period before the public could provide input on Kentucky's decision to amend its 1115 waiver to include premiums and various enrollment restrictions and penalties (along with a work reporting requirement as a condition of eligibility).^{30,31}

In these two recent instances, interested parties in Indiana and Kentucky were not afforded an opportunity to provide meaningful input to their state before the state submitted major changes to Medicaid eligibility and cost-sharing. These lapses in state-level public notice and comment not only violated the framework established by Congress under the Social Security Act—requiring a "meaningful level of public input" at both the State- and CMS- levels³²—but they stood against contemporaneous statements from CMS in supporting an open and transparent process. In March 2017, CMS sent a letter to state governors describing its vision for Medicaid demonstrations under Section 1115, stating:

"we remain committed to certain mechanisms, which ensure state accountability for the outcomes produced by the Medicaid program...reasonable public input processes and transparency guidelines provide states an opportunity to consider the views of Medicaid enrollees and stakeholders and gather input that may support continuous improvement of the program."³³

This new PRA submission by CMS renews that spirit of transparency and public engagement by stating:

"This collection is necessary to ensure that states comply with regulatory and statutory requirements related to the development, implementation and evaluation of demonstration projects."³⁴

We agree with CMS that this information collection is necessary, and well within the government's right to collect under the PRA, and we strongly recommend that CMS ensure all public comments periods are conducted in accordance with current Medicaid law. Given recent lapses in public transparency into the waiver process (as outlined

above and as examined in the 2019 GAO report), we hope this PRA notice stands as a recommitment to CMS' obligations under the Social Security Act to keep the Section 1115 demonstration process transparent and open to the public.

In conclusion, we support CMS' desire to continue to collect information related to 1115 waivers, including the underlying obligations for CMS to enforce state-level public notice and comment procedures which hold states accountable to Medicaid-eligible populations and other stakeholders.

For questions or comments regarding the recommendations made in this letter, please reach out to Mary-Beth Malcarney, Senior Advisor on Medicaid Policy, Families USA at: mmalcarney@familiesusa.org.

Thank you for your time and consideration.

Sincerely,



Sophia Tripoli

Senior Director of Health Policy

Families USA

¹ Paperwork Reduction Act, 44 U.S.C. § 3501 et seq. Public Law 104-13, 104th Congress, <https://www.govinfo.gov/content/pkg/PLAW-104publ13/html/PLAW-104publ13.htm>

² 42 U.S. Code § 1315(a)(1), https://www.ssa.gov/OP_Home/ssact/title11/1115.htm.

³ 42 U.S. Code § 1315(d)(1), https://www.ssa.gov/OP_Home/ssact/title11/1115.htm.

⁴ Under long-standing policy and practice (although not required by statute), waivers must be “budget neutral” to the federal government over the course of the waiver. This means demonstration projects cannot result in Medicaid costs to the federal government that are greater than what the federal government’s Medicaid costs would likely have been absent the demonstration “Section 1115 Demonstration Budget Neutrality,” Medicaid and CHIP Payment Access Commission, December 2021, <https://www.macpac.gov/wp-content/uploads/2021/12/Section-1115-Demonstration-Budget-Neutrality.pdf>.

⁵ “Medicaid Waiver Tracker: Approved and Pending Section 1115 Waivers by State,” KFF, February 7, 2025, <https://www.kff.org/medicaid/issue-brief/medicaid-waiver-tracker-approved-and-pending-section-1115-waivers-by-state/>.

⁶ “Medicaid Waiver Tracker: Approved and Pending Section 1115 Waivers by State,” KFF, February 7, 2025, <https://www.kff.org/medicaid/issue-brief/medicaid-waiver-tracker-approved-and-pending-section-1115-waivers-by-state/>.

⁷ See Medicaid Program; Demonstration Proposals Pursuant to Section 1115(a) of the Social Security Act; Policies and Procedures, 59 Fed. Reg. 49,249 (Sept. 27, 1994).

⁸ “Medicaid Demonstrations: Approvals of Major Changes Need Increased Transparency” (GAO-19-315), Government Accountability Office, April 2019, <https://www.gao.gov/assets/gao-19-315.pdf>.

⁹ See GAO, Medicaid and SCHIP: Recent HHS Approvals of Demonstration Waiver Projects Raise Concerns, GAO-02-817 (Washington, D.C.: July 12, 2002), <https://www.gao.gov/assets/d02817.pdf>; and Medicaid Demonstration Waivers: Lack of Opportunity for Public Input during Federal Approval Process Still a Concern, GAO-07-694R (Washington, D.C.: July 24, 2007), <https://www.gao.gov/assets/gao-07-694r.pdf>.

¹⁰ 42 U.S. Code §§ 1315(d)(2)(A), 1315(d)(2)(C), https://www.ssa.gov/OP_Home/ssact/title11/1115.htm.

¹¹ 42 U.S. Code § 1315(d)(1), https://www.ssa.gov/OP_Home/ssact/title11/1115.htm.

¹² 42 CFR § 431.408, <https://www.law.cornell.edu/cfr/text/42/431.408>.

¹³ 42 CFR § 431.412, <https://www.law.cornell.edu/cfr/text/42/431.412>.

¹⁴ 42 CFR § 431.420, <https://www.law.cornell.edu/cfr/text/42/431.420>.

¹⁵ 42 CFR § 431.424, <https://www.law.cornell.edu/cfr/text/42/431.424>.

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- ¹⁶ “Public Comment Summary for the Draft 1115 Waiver Renewal application,” New Mexico Human Services Department, October 2017, https://www.hca.nm.gov/wp-content/uploads/Appendix-D_1-Public-Comments-Summary-and-Responses-1.pdf.
- ¹⁷ Mid-Point Evaluation Section 1115 Substance Use Disorder Demonstration Kentucky Cabinet for Health & Family Services Department of Medicaid Services, Center for Health Innovation Northern Kentucky University, April 12, 2021, <https://www.chfs.ky.gov/agencies/dms/BHI/SUDApprovedMidPointAssess.pdf>.
- ¹⁸ Paperwork Reduction Act, 44 U.S.C. § 3501(2). Public Law 104-13, 104th Congress, <https://www.govinfo.gov/content/pkg/PLAW-104publ13/html/PLAW-104publ13.htm>
- ¹⁹ Paperwork Reduction Act, 44 U.S.C. § 3501(4). Public Law 104-13, 104th Congress, <https://www.govinfo.gov/content/pkg/PLAW-104publ13/html/PLAW-104publ13.htm>
- ²⁰ Letter to U.S. Department of Health and Human Services, State of Utah, Office of the Governor, November 1, 2019, <https://medicaid.utah.gov/Documents/pdfs/Utah%201115%20Waiver%20Amendment-Fallback%20Plan.pdf>.
- ²¹ “Utah 1115 Demonstration Waiver Project Number: 11-W-00145/8 & 21-W-0054/8,” Utah Department of Health, <https://medicaid.utah.gov/Documents/pdfs/Utah%201115%20PCN%20Waiver%20Monitoring%20Report-DY18Q2-Quarterly%20Report%20Final.pdf>.
- ²² Letter to Utah Division of Medicaid and Health Financing, Centers for Medicare and Medicaid Services, December 23, 2019, <https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/ut-primary-care-network-amendment-appvl-12232019.pdf>.
- ²³ “Medicaid Demonstrations: Approvals of Major Changes Need Increased Transparency,” Government Accountability Office, April 2019. <https://www.gao.gov/assets/d19315.pdf>.
- ²⁴ “Medicaid Demonstrations: Approvals of Major Changes Need Increased Transparency,” Government Accountability Office, April 2019. <https://www.gao.gov/assets/d19315.pdf>.
- ²⁵ Hinton, E & Diana A, Medicaid Section 1115 Waivers: The Basics, KFF, January 24, 2025, [https://www.kff.org/medicaid/issue-brief/medicaid-section-1115-waivers-the-basics/#:~:text=The%20Affordable%20Care%20Act%20\(ACA,%2C%20public%20input%2C%20and%20evaluation.&text=Regulations%20require%20public%20notice%20and,and%20extensions%20of%20existing%20waivers.](https://www.kff.org/medicaid/issue-brief/medicaid-section-1115-waivers-the-basics/#:~:text=The%20Affordable%20Care%20Act%20(ACA,%2C%20public%20input%2C%20and%20evaluation.&text=Regulations%20require%20public%20notice%20and,and%20extensions%20of%20existing%20waivers.)
- ²⁶ Amendment Request to Healthy Indiana Plan (HIP) Section 1115 Waiver Extension Application (Project Number 11-W-00296/5), Indiana Family and Social Services Administration, May 24, 2017, https://www.in.gov/fssa/hip/files/HIP_Amendment_FINAL_Publication_Version.pdf.
- ²⁷ Letter to Indiana Family and Social Services Administration, Centers for Medicaid and Medicare Services, June 9, 2017, <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/in/Healthy-Indiana-Plan-2/in-healthy-indiana-plan-support-20-complete-ltr-06092017.pdf>.
- ²⁸ Kentucky HEALTH § 1115 Demonstration Modification Request, Commonwealth of Kentucky, Office of the Governor, July 2, 2017, <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ky/ky-health-pa2.pdf>.
- ²⁹ Letter to Indiana Family and Social Services Administration, Centers for Medicaid and Medicare Services, June 9, 2017, <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/in/Healthy-Indiana-Plan-2/in-healthy-indiana-plan-support-20-complete-ltr-06092017.pdf>.
- ³⁰ Kentucky HEALTH § 1115 Demonstration Modification Request, Commonwealth of Kentucky, Office of the Governor, July 2, 2017, <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ky/ky-health-pa2.pdf>.
- ³¹ Proposed Changes to Medicaid Expansion in Kentucky, KFF, August 4, 2017, https://www.kff.org/medicaid/fact-sheet/proposed-changes-to-medicaid-expansion-in-kentucky/#endnote_link_227321-4.
- ³² 42 U.S. Code §§ 1315(d)(2)(A), 1315(d)(2)(C), https://www.ssa.gov/OP_Home/ssact/title11/1115.htm.
- ³³ Letter from Secretary Price and CMS Administrator Verma to governors, March 14, 2017, <https://www.hhs.gov/sites/default/files/sec-price-admin-verma-ltr.pdf>.
- ³⁴ Agency Information Collection Activities: Submission for OMB Review; Comment Request, 90 Fed. Reg. 8800 (February 3, 2025), <https://www.govinfo.gov/content/pkg/FR-2025-02-03/pdf/2025-02168.pdf>.