Georgetown University
Health Policy Institute
CENTER FOR CHILDREN
AND FAMILIES

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VIA ELECTRONIC SUBMISSION

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RE: Oregon Health Plan 1115 Demonstration Waiver Renewal and Amendment

To Whom It May Concern:

Thank you for the opportunity to comment on the draft renewal application for the "Oregon Health Plan" 1115 demonstration waiver. The Georgetown University Center for Children and Families (CCF) is an independent, nonpartisan policy and research center founded in 2005. As part of the McCourt School of Public Policy, Georgetown CCF conducts research, develops strategies, and offer solutions to improve the health of America's children and families, especially those with low and moderate incomes.

As explained below, we strongly support the proposal to provide multiple years of continuous eligibility for children and adults. We commend Oregon for leading the country with this request. We also applaud the state's focus on and investments in health equity, which would work to address racial and health disparities in the state.

However, we strongly oppose the request to waive the Early and Periodic Screening, Diagnostic Treatment (EPSDT) benefit for children over age one, which is critical to ensure children receive all services necessary for their growth and development. Waiving this benefit serves no demonstration purpose and is potentially harmful to children's health and development. We also strongly oppose the request to waive the three-month retroactive coverage period for almost all Medicaid beneficiaries as well as the proposed closed formulary and exclusions of certain prescription drugs. These provisions reduce coverage and services for children and their families and do not promote the objectives of Medicaid. The flexibilities requested related to managed care raise serious concerns, especially for the potential effects on beneficiaries, and some are not allowable under a section 1115 demonstration. Finally, Oregon does not enumerate the specific waiver and expenditure authorities needed for its renewal request and therefore fails to comply with federal regulations for an extension application.

Multi-year continuous eligibility would reduce gaps in coverage and improve continuity of care.

Oregon already provides 12-month continuous eligibility to children in its Medicaid program and Children's Health Insurance Program (CHIP) at state option. In its proposal, the state would test extending the length of the continuous eligibility period by providing continuous coverage for children until the age of six and two years of continuous eligibility for all beneficiaries age six and up with the goal of maximizing access to coverage. *We strongly support Oregon's proposals on continuous eligibility.* Oregon is the first state to make such a request – and we commend you for the state's bold vision. Such a proposal is exactly the kind of request that section 1115 demonstrations are well-suited for, and we will strongly encourage CMS to approve it.

Continuous eligibility is a significant tool to reduce gaps in coverage and enhance continuity of care. Covering children from birth to six can help form the backbone of a new nationwide commitment to children's health.[1] The policy improves health status and well-being, promotes health equity, allows for better measurement of quality of care, and reduces administrative burdens.[2] Extending continuous eligibility for longer periods for children would promote consistent access to health care to address any concerns that may affect school readiness, especially for young children who are at the most critical development period.[3] The benefits of continuous eligibility are also afforded to adults. As CMS noted in its 2013 guidance, providing continuous eligibility to parents and other adults results in greater stability of coverage for the whole family.[4]

The proposal would also help reduce "churn" for both child and adult beneficiaries. Individuals with Medicaid are at risk of moving on and off coverage due to temporary changes in income that affect eligibility; continuous eligibility can help mitigate the effects of this income volatility that result in churn. Individuals that experience churn or other coverage disruptions are more likely to delay care and have periods of uninsurance.[5] According to recent data from MACPAC, even in states with 12-month continuous eligibility, almost three percent of children in Medicaid and over seven percent of children

[1] Kelly Whitener and Joan Alker, "Covering All Children," Georgetown University Center for Children and Families, February 2020, https://ccf.georgetown.edu/wp-content/uploads/2020/02/CoverAllKidsFinal.pdf.
[2] Tricia Brooks and Allexa Gardner, "Continuous Coverage in Medicaid and CHIP," Georgetown University Center for Children and Families, July 2021, https://ccf.georgetown.edu/wp-content/uploads/2021/07/Continuous-Coverage-Medicaid-CHIP-final.pdf.
[3] Elisabeth Wright Burak, "Promoting Young Children's Healthy Development in Medicaid and thee Children's Health Insurance Program," Georgetown University Center for Children and Families, October 2018, https://ccf.georgetown.edu/wp-content/uploads/2018/10/Promoting-Healthy-Development-v5-1.pdf.
[4] Center for Medicaid and CHIP Services, "SHO #13-003: Facilitating and CHIP Enrollment and Renewal in 2014," May 2013 https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/downloads/SHO-13-003.pdf.
[5] Sarah Sugar, *et. al*., "Medicaid Churning and Continuity of Care: Evidence and Policy Considerations Before and After the COVID-19 Pandemic," HHS Assistant Secretary for Planning and Evaluation, April 12, 2021, https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//199881/medicaid-churning-ib.pdf.

in CHIP had less than a full year of coverage.[6] Research has shown that children have the highest rates of Medicaid enrollment churn compared to other eligibility groups.[7]

We encourage you to examine how providing multiple years of continuous eligibility affects administrative cost for the state and CCO's. In Montana, state officials reported administrative spending savings and fewer staff hours needed to process individuals moving on and off the program as a result of adopting continuous eligibility for adults.[8]

Significant investments in health equity would address racial disparities the state.

We applaud the state's intent to center on health equity in its request. The proposal would include several significant changes to invest in community investment collaboratives and utilizing Traditional Health Workers to promote culturally responsive care. We are strongly supportive of the state's goals and efforts to reduce racial disparities.

The state seeks to engage communities as a key part of its health equity investments, specifically in the proposed community investment collaboratives (CICs). CICs would serve as a "community-led accountability structure" that would help oversee all spending on health equity and are intended to focus on populations that have been most harmed by health inequities including communities of color, people with disabilities, and immigrant communities, among others. Though progress has been made in reducing racial disparities, people of color still experience worse health outcomes and lower coverage rates than white individuals.[9] By engaging in a community-based approach to health equity, the state will ensure spending truly addresses the needs and barriers faced by populations that have been historically marginalized and can help improve persistent disparities.

Under the proposal, Traditional Health Workers would be utilized to improve access to services particularly among beneficiaries experiencing life transitions. Traditional Health Workers would include community health workers, peer wellness and support specialists, and doulas. These providers may be more trusted by beneficiaries and can assist them in receiving culturally competent care. For example, doulas have been found to be beneficial to women of color or with low incomes; expanding access to these providers can help reduce health disparities.[10]

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[6] MACPAC, "An Updated Look at Rates of Churn and Continuous Coverage in Medicaid and CHIP," October 2021, https://www.macpac.gov/wp-content/uploads/2021/10/An-Updated-Look-at-Rates-of-Churn-and-Continuous-Coverage-in-Medicaid-and-CHIP.pdf.

[7] Bradley Corallo, *et al.,* "Medicaid Enrollment Churn and Implications for Continuous Coverage Policies,"Kaiser Family Foundation, December 14, 2021, https://www.kff.org/medicaid/issue-brief/medicaid-enrollment-churn-and-implications-for-continuous-coverage-policies/.

[8] Niranjana Kowlessar *et al*., "Federal Evaluation of Montana Health and Economic Livelihood Partnership (HELP): Summative Evaluation Report," Social & Scientific Systems, November 30, 2020, https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/summative-eval- rpt-montana-2020.pdf.

[9] Nambi Ndugga and Samantha Artiga, "Disparities in Health and Health Care: 5 Key Questions and Answers," Kaiser Family Foundation, May 11, 2021, https://www.kff.org/racial-equity-and-health-policy/issue-brief/disparities-in-health-and-health-care-5-key-question-and-answers/.

[10] Tomas Guarnizo and Maggie Clark, "Lessons Learned from Early State Experiences Using Medicaid to Expand Acceses to Doula Care," Georgetown University Center for Children and Families, December 15, 2021,

Waiving the EPSDT benefit risks children's access to necessary services.

Oregon is requesting to continue waiving the Early and Periodic Screening, Diagnostic Treatment benefit, Medicaid's comprehensive, child-focused benefit. As you know, children represent a substantial portion of Medicaid beneficiaries in the state, with 469,000 children under 19 currently covered.[11] In 2019, 36.8 percent of children in Oregon were covered by Medicaid.[12] EPSDT guarantees that children and young adults under age 21 receive the full scope of services necessary for their growth and healthy development. Oregon is the only state in the country to have a limit in place on these benefits for children under 19.

EPSDT ensures children with Medicaid coverage are screened regularly for health problems and developmental delays, *and* treatment must be provided as needed. Without this critical benefit, children are at risk of not receiving necessary services. This risk is especially true since the Oregon Health Plan's covered services are determined by the state's "prioritized list of health services," which excludes services that fall below the designated funding line. On the state's current prioritized list of 662 services, only the first 471 are covered.[13]

Medicaid's EPSDT benefit is especially important for children with special health care needs or disabilities. These children may have more extensive health care needs or chronic conditions that require types or amounts of services that most children do not generally need.[14] EPSDT is also important for children of color who are more likely to have Medicaid coverage. In Oregon, approximately 60 percent of the child population who are American Indian/Alaskan Native, Black, or Latino are covered by Medicaid (57 percent of AIAN children; 60 percent of Black children; 65 percent of Latino children).[15] Limiting their benefits undermines the very core of what Oregon purports to do with its demonstration—advance health equity and maximize equitable access to coverage.

Oregon has been restricting EPSDT benefits since the inception of the OHP demonstration in 1994. The purpose of a section 1115 demonstration is to test new approaches that promote the objectives of Medicaid. While there was never a justification for stripping children of their entitlement to EPSDT, any potential experiment has long

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https://ccf.georgetown.edu/2021/12/15/lessons-learned-from-early-state-experiences-using-medicaid-to-expand-access-to-doula-care/.

[11] Oregon Health Authority, "Monthly Medicaid Population Report, August 2021 (Preliminary)," https://www.oregon.gov/oha/HSD/OHP/DataReportsDocs/August%202021%20Physical%20Health%20Service%20Delivery%20by%20Age%20Group.pdf.

[12] Kaiser Family Foundation, "Health Insurance Coverage of Children 0-18," https://www.kff.org/other/state-indicator/children-0-18/?currentTimeframe=0&selectedRows=%7B%22states%22:%7B%22oregon%22:%7B%7D%7D%7D&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.

[13] Oregon Health Authority, "Prioritized List of Health Services," https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Prioritized-List.aspx.

[14] Tricia Brooks and Kelly Whitener, "At Risk: Medicaid's Child-Focused Benefit Structure Known as EPSDT," Georgetown University Center for Children and Families, June 2017, https://ccf.georgetown.edu/wp-content/uploads/2017/06/EPSDT-At-Risk-Final.pdf.

[15] Tricia Brooks and Allexa Gardner, "Snapshot of Children with Medicaid by Race and Ethnicity, 2018," Georgetown University Center for Children and Families, July 2020, https://ccf.georgetown.edu/wp-content/uploads/2020/07/Snapshot-Medicaid-kids-race-ethnicity-v4.pdf.

expired. Denying needed health care to children does not serve any valid experimental purpose and should not be continued.

Furthermore, in the application, there is no explanation of the services that would not be covered nor what protections the state has in place to ensure that restrictions on EPSDT services do not have a disparate impact on children of color. With the omission of these details, Oregon has not explained the potential impact the waiver has, and will continue to have, which does not allow for full public engagement on the proposal.

We urge you to remove this waiver as part of Oregon's extension request.

The proposed closed formulary and exclusion of certain prescription drugs from coverage undermines Medicaid.

The state is seeking to adopt a closed prescription drug formulary for adult beneficiaries, with only a minimum of one drug per class. Cost, not just clinical efficacy, would be a key criteria. Separately, the proposal would also exclude drugs, including but not limited to those coming to the market through the Food and Drug Administration's accelerated approval pathway, that the state determines to have "limited or inadequate clinical efficacy" as well as drugs that are determined to have "no incremental clinical benefit" compared to others in its therapeutic class. Unlike the broader closed formulary authority the state is seeking, this proposal would apply to pediatric drugs as well.

These proposals are a drastic change to the current requirement under the Medicaid Drug Rebate Program that Medicaid programs must cover nearly all FDA-approved outpatient drugs. As a result, they will likely restrict beneficiary access to needed prescription drugs; this does not promote the objectives of Medicaid but rather undermines them.

The proposal fails to outline any appeals process to allow beneficiaries to obtain off-formulary drugs under either provision, let alone describe in detail how such a process would work and the criteria for determining whether off-formulary coverage would be approved. The proposed changes to the Medicaid prescription drug benefit would likely be most detrimental to beneficiaries with multiple or complicated health conditions including individuals with chronic conditions or with disabilities who require very high-cost specialty drugs.

The state also holds up Medicare Part D as an example of a program that is permitted to operate a closed formulary. Yet, the proposal is actually more restrictive than Medicare Part D as it does not include some key protections that are a requirement in Medicare Part D. First, Oregon's closed formulary would only cover at least one drug per therapeutic class compared to two in Medicare Part D. Also, the state does not include any exemptions for six "protected" classes of drugs—anti-depressants, anticonvulsants, antipsychotics, immunosuppressants, antineoplastics, and antiretroviral drugs—that Medicare Part D is required to cover.

While the first proposal would maintain an open formulary for children, the state does not define the age ranges that comprise the child population. Specifically, it is unclear whether 19-and-20-year-olds are considered children or if they are included in the adult eligibility category. This is particularly important because, with the waiver of EPSDT benefits (which normally apply to individuals under 21), 19-and-20-year-olds may have their access to prescription drugs restricted. And, as noted above, the second proposal would apply not just to adults but also to children.

The state claims it is pursuing the proposed prescription drug changes in order to obtain larger supplemental rebates from drug manufacturers. It is important to recognize that Medicaid already obtains the lowest prices, net of rebates and discounts, compared to other federal programs and agencies, including not just Medicare Part D but also the Department of Veterans Affairs.[16] This is driven by the mandatory rebates required under the highly successful Medicaid Drug Rebate Program, with supplemental rebates only a small share of total rebates.[17] It is not clear the proposal would actually result in significant new savings, as states already have levers such as preferred drug lists and prior authorization when negotiating with manufacturers today. The proposal would therefore likely only generate significant savings if the state used its two proposed new authorities to substantially restrict access to needed prescription drugs and thus reduce utilization and spending.

There is no research or experimental justification to reduce prescription drug coverage for beneficiaries and it is inconsistent with the purpose of Medicaid. In fact, federal courts have ruled that "[a] simple benefits cut, which might save money, but has no research or experimental goal, would not satisfy" the section 1115 requirement for an experiment.[18]

Eliminating retroactive coverage does not promote the objectives of Medicaid.

Under the proposal, almost all Medicaid beneficiaries including pregnant women, infants, and children, would not have protection from the financial burden of medical debt resulting from the costs of care they need during the three months prior to applying for Medicaid. With the continued waiver of three-month retroactive coverage, low-income children and their families are exposed to medical bills that may be financially devastating. The policy reduces coverage and therefore fails to promote the principal objective of Medicaid.

Furthermore, while we do not believe there was ever a legitimate purpose for eliminating retroactive coverage, the state's continued waiving of coverage is well past the

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[16] Edwin Park, "New CBO Study Compares Net Prices for Brand-Name Drugs Among Federal Programs, Finds Medicaid Gets Largest Discounts," Georgetown University Center for Children and Families, February 22, 2021, https://ccf.georgetown.edu/2021/02/22/new-cbo-study-compares-net-prices-for-brand-name-drugs-among-federal-programs-finds-medicaid-gets-largest-discounts/.
[17] Edwin Park, "How to Strengthen the Medicaid Drug Rebate Program to Address Rising Medicaid Prescription Drug Costs," Georgetown University Center for Children and Families, January 9, 2019, https://ccf.georgetown.edu/2019/01/09/how-to-strengthen-the-medicaid-drug-rebate-program-to-address-rising-medicaid-prescription-drug-costs/.
[18] *Beno v. Shalala,* 30 F. 3d 1057 (9th Cir. 1994)

point of being an experiment; the waiver has been in place for *over two decades*. The state does not provide a hypothesis for this policy nor does it include the policy in its proposed evaluation. The waiver of retroactive coverage does not meet the statutory requirement to be an experiment that is likely to assist in furnishing coverage. In fact, it does the opposite. There is no justification to continue waiving retroactive coverage, especially when the state identifies reducing gaps in coverage as one of its goals of the renewal request, and that the policy would disproportionately affect people of color, which is counter to the efforts to reduce health inequities.

The requested managed care flexibilities are fundamentally flawed and several lack adequate details.

The proposal contains multiple requests related to new or additional flexibilities in managed care. While we are supportive of the intent of Oregon's initiatives aiming to expand access to services addressing health-related social needs (HRSN), we have serious concerns regarding some of the waiver requests related to managed care.

Medicaid regulations at 42 C.F.R. § 438.5(d) require that managed care rate-setting trend factors "be reasonable and developed in accordance with generally accepted actuarial principles and practices" and "be developed primarily from actual experience of the Medicaid population or from a similar population." We do not believe the state's proposed trend rates (ranging from 3.0 to 3.4%) meet any of these standards. It is particularly important, legally and practically, that managed care rates be actuarially sound, as defined in the law at section 1903(m)(2)(A)(iii) of the Social Security Act, and based upon the actual costs of providing services to enrollees. While CMS has historically waived freedom of choice many times, there is no authority for CMS to waive managed care standards or section 1903 through section 1115. Approving rates that are not actuarially sound also does not promote the objectives of Medicaid.

More broadly, while we do not object in principle to the state considering HRSN-related services in the rate-setting and MLR processes, we do not support such proposals when the HRSN services replace needed state plan services. We are concerned that Oregon's proposal, which includes prioritized lists of services, would do that. We recommend the state make two adjustments to its proposal. First, we recommend the state drop the list of prioritized services. This provision is clearly no longer needed as the state projects its accrued historical savings will grow to more than $11 billion over the life of the demonstration. Second, we recommend that the state develop rates based on all state plan services *and* supplement those rates by adding HRSN-services. There is no statutory barrier to such an approach, and effective investments will lead to state plan services reductions over time based on beneficiaries' reduced need, as opposed to artificial timelines and budgets.

We recommend the state retract several waiver provisions related to mandatory enrollment and prohibiting disenrollment that violate the statutory standards set out in sections 1903 and 1932 of the Social Security Act. These provisions are not waivable and

exist to protect at-risk populations, such as older adults, persons with disabilities, and individuals who are newly enrolled into managed care plans.

Finally, we are unable to comment on several of the proposed waiver authorities which are undefined but raise questions. The state suggests that it is considering options for "risk-sharing arrangements" and "brokering re-insurance or stop-loss insurance," and lists several critical Medicaid requirements, including contract requirements, access standards, and solvency standards, which may need to be waived to pursue the policy. The state should not pursue such policies without offering the public a chance to comment on concrete and detailed policies and waiver requests, and even then, we again note that there are limits to what the state can waive through section 1115 (as described above). It is similarly unclear what the state's request to "[i]mplement Value-based payment methodologies" by waiving 42 C.F.R. § 438.6 is intended to accomplish, as no waiver is generally needed to implement § 438.6 strategies. Thus, we are unable to comment on this proposal.

The application does not meet federal requirements for the state public notice process.

As part of a section 1115 extension application, under federal regulations Oregon is required to provide the "the specific waiver and expenditure authorities that [it] believes to be necessary to authorize the demonstration."[19] The state's application does include a section on waiver and expenditure authorities; however, *the section does not describe the specific authorities that would be needed to implement its new and existing proposals*. For example, the state says that for new provisions it is requesting, it will determine with CMS whether additional waiver authority is needed to authorize those provisions. The failure to explain the authorities necessary to implement its requests undercuts the ability of the public to understand the proposal and meaningfully comment on it. Oregon should revise its application to specify the authorities needed for its demonstration and reopen the state comment period.

Thank you for consideration of our comments. If you need any additional information, please contact me at jca25@georgetown.edu.

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[19] 42 CFR § 431.408