



April 13, 2022

Secretary Xavier Becerra  
U.S. Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, DC 20201

Re: Oregon Health Plan Extension Application

Dear Secretary Becerra,

Thank you for the opportunity to comment on Oregon's renewal application for the "Oregon Health Plan" section 1115 demonstration. 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 offers solutions to improve the health of America's children and families, especially those with low and moderate incomes.

Section 1115(a) of the Social Security Act gives the Secretary the power to waive compliance with the requirements of section 1902 if a proposal "is likely to assist in promoting the objectives" of Medicaid. As such, section 1115 demonstrations should not be approved unless they are likely to promote coverage and access to care and are consistent with Executive Order 14009 (Strengthening Medicaid and the Affordable Care Act) and Executive Order 14070 (Continuing to Strengthen Americans' Access to Affordable, Quality Health Coverage).<sup>1</sup> Section 1115 demonstrations can also play an important role in reducing racial disparities and should be consistent with the objectives of Executive Order 13985 (Advancing Racial Equity and Support for Underserved Communities Through the Federal Government).<sup>2</sup> We believe that some provisions in Oregon's application fulfill these objectives and will benefit enrollees. In particular, we strongly support the proposal to provide multiple years of continuous eligibility for children and adults and commend the state for leading the country with this request. However, while we applaud the state's decision to drop its request for a waiver of the Early, Periodic Screening and Diagnostic Treatment benefit (EPSDT), we believe that any continued use of the prioritized list is incompatible with the EPSDT benefit and does not serve the objectives of Medicaid.

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<sup>1</sup> Executive Order No. 14009, 86 CFR 7793 (2021), <https://www.federalregister.gov/documents/2021/02/02/2021-02252/strengthening-medicaid-and-the-affordable-care-act>; Executive Order No. 14070, 87 CFR 20689 (2022), <https://www.federalregister.gov/documents/2022/04/08/2022-07716/continuing-to-strengthen-americans-access-to-affordable-quality-health-coverage>.

<sup>2</sup> "Request for Action on Pending Section 1115 Demonstrations to Reduce Racial Disparities," Letter to Secretary of Health and Human Services, July 2020, <https://ccf.georgetown.edu/wp-content/uploads/2020/12/Medicaid-Supporting-Black-Women-Sign-On-Letter.pdf>; Executive Order No. 13985, 86 CFR 7009 (2021), <https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government>.

Further, we have concerns that the state’s proposals regarding managed care and limitations on accelerated approval drugs would set untenable precedents. We urge CMS to work with the state to implement the numerous positive provisions but drop or repair the provisions that do not support access to coverage.

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

Oregon has provided a 12-month continuous eligibility period for children enrolled in Medicaid or CHIP since 2009. In this application, the state seeks to maximize coverage by providing continuous eligibility for young children until the age of six and two years of continuous eligibility for all enrollees ages six and up. We believe that extending continuous eligibility would promote health equity, improve access to care, and strengthen program efficiency. This proposal will promote the objectives of Medicaid and is the type of request for which section 1115 demonstrations should be used. *We strongly urge CMS to approve the request to extend continuous eligibility.*

Consistent with the goals of Executive Order 13985 and the strategic vision laid out by CMS Administrator Chiquita Brooks-LaSure and CMCS Director Daniel Tsai, lengthening continuous eligibility for children and adults has the potential to remedy disparities in coverage.<sup>3</sup> Individuals with Medicaid are at risk of moving off and on coverage due to temporary changes in income that affect eligibility, a phenomenon known as “churn.” Recent research shows that children are among the eligibility groups most likely to experience churn and that Asian, Black, and Hispanic children are more likely to be uninsured for part or all of the year than non-Hispanic white children.<sup>4</sup> The outcome of the Families First Coronavirus Response Act (FFCRA) maintenance of effort provisions in Oregon hint at the potential of the continuous eligibility provisions to mitigate the disproportionate impact of churn and uninsurance. The state’s overall uninsured rate reached a record low in 2021 (4.6 percent).<sup>5</sup> And, when disaggregated by race/ethnicity, Black Oregonians saw the largest percentage point reduction between 2019 and 2021.<sup>6</sup>

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<sup>3</sup> Executive Order No. 13985, Op cit.; Chiquita Brooks-LaSure and Daniel Tsai, “A Strategic Vision for Medicaid and the Children’s Health Insurance Program (CHIP),” *Health Affairs Blog*, November 16, 2021, <https://www.healthaffairs.org/doi/10.1377/forefront.20211115.537685/full/>.

<sup>4</sup> 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/>; Aubrianna Osorio and Joan Alker, “Gaps in Coverage: A Look at Child Health Insurance Trends,” Georgetown University Center for Children and Families, <https://ccf.georgetown.edu/2021/11/22/gaps-in-coverage-a-look-at-child-health-insurance-trends/>.

<sup>5</sup> Jeremy Vandehey and Dave Baden, “Oregon Health Plan Post-Public Health Emergency Eligibility Redeterminations Planning,” Oregon Health Authority Presentation to House Rules Committee, February 17, 2022, <https://www.oregon.gov/oha/HPA/HP-MAC/MACmeetings/2.0%20Oregon%20Redeterminations%20Briefing%20House%20Rules%202-17-22%20FINAL.pdf#page=4>.

<sup>6</sup> Oregon Health Authority, “Types of Uninsurance,” January 2022, <https://visual-data.dhs.oha.state.or.us/t/OHA/views/OregonUninsuranceRates/Uninsurance?%3Aiid=2&%3AisGuestRedirectFromVizportal=y&%3Aembed=y>.

While this decrease in uninsurance may be the result of multiple factors, the FFCRA continuous eligibility provision was likely a major factor in this decline.<sup>7</sup>

Continual access to care is vital for the healthy development of young children. Children with unaddressed conditions such as asthma, vision or hearing impairment, nutritional deficiencies, and mental health challenges are unable to succeed in kindergarten and beyond.<sup>8</sup> To catch early warning signs of these problems, the American Academy of Pediatrics recommends that young children receive at least 15 well-child visits in their first six years of life.<sup>9</sup> Ensuring that children under six have stable coverage would improve access to the necessary preventive care and developmental screenings that occur during these visits and set the stage for better long-term outcomes.<sup>10</sup> Stability in coverage would also support connection to a medical home and foster a trusted relationship between provider and family, promoting optimal care.<sup>11</sup> Even if a child does not become uninsured, when their family frequently switches coverage they must navigate different provider networks and prior authorization requirements, which can lead to gaps in care.<sup>12</sup>

For older children and adults, continuous eligibility can also improve health outcomes by ensuring timely access to care. People who experience disruptions in coverage are more likely to delay care.<sup>13</sup> Continuous eligibility, on the other hand, will support uninterrupted completion of treatment plans and prescription drug regimens, likely lowering hospitalizations and per member per month (PMPM) costs. In New York, implementing a one-year continuous eligibility period for adult beneficiaries led to declines in inpatient hospital admissions and overall PMPM costs.<sup>14</sup> And, stable access to coverage protects against the medical debt that can accrue during gaps in coverage and

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<sup>7</sup> Matthew Buettgens *et al.*, “What Will Happen to Medicaid Enrollees’ Health Coverage after the Public Health Emergency?,” Urban Institute, March 2022, <https://www.urban.org/research/publication/what-will-happen-medicaid-enrollees-health-coverage-after-public-health-emergency>.

<sup>8</sup> Delaney Gracy *et al.*, “Health Barriers to Learning: The Prevalence and Educational Consequences in Disadvantaged Children, A Review of the Literature,” January 2017, <https://www-childrenshealthfund.b-cdn.net/wp-content/uploads/2017/02/HBL-Literature-Review-2-2-2017.pdf>.

<sup>9</sup> American Academy of Pediatrics, “Recommendations for Preventive Pediatric Health Care,” March 2021, [https://downloads.aap.org/AAP/PDF/periodicity\\_schedule.pdf](https://downloads.aap.org/AAP/PDF/periodicity_schedule.pdf).

<sup>10</sup> Elisabeth Wright Burak, “Promoting Young Children’s Healthy Development in Medicaid and CHIP,” Georgetown University Center for Children and Families, October 17, 2018, <https://ccf.georgetown.edu/2018/10/17/promoting-young-childrens-healthy-development-in-medicaid-and-the-childrens-health-insurance-program-chip/>.

<sup>11</sup> American Academy of Pediatrics, “Overview of Data Related to Pediatric Medical Home,” September 29, 2017, <https://medicalhomeinfo.aap.org/Documents/Overview%20of%20Data%20Related%20to%20the%20Pediatric%20Medical%20Home%20NCMHI%20Update%209.29.17.pdf>.

<sup>12</sup> Sarah Sugar *et al.*, “Medicaid Churning and Continuity of Care: Evidence and Policy Considerations Before and After the COVID-19 Pandemic,” Assistant Secretary for Planning and Evaluation Office of Health Policy, April 12, 2021, <https://aspe.hhs.gov/sites/default/files/private/pdf/265366/medicaid-churning-ib.pdf>.

<sup>13</sup> Sarah Sugar *et al.*, Op cit.

<sup>14</sup> Harry H. Liu *et al.*, “New York State 1115 Demonstration Independent Evaluation: Interim Report,” Rand Corporation, 2021, [https://www.health.ny.gov/health\\_care/medicaid/redesign/mrt2/ext\\_request/docs/2021-08-03\\_1115\\_demo\\_eval.pdf#page=110](https://www.health.ny.gov/health_care/medicaid/redesign/mrt2/ext_request/docs/2021-08-03_1115_demo_eval.pdf#page=110).

disproportionately impacts individuals of color.<sup>15</sup> Improved financial security, in turn, leads to lower levels of toxic stress and the associated physiological symptoms.<sup>16</sup>

Finally, continuous eligibility has the potential to free up administrative resources and to improve quality measurement. After adopting one year of continuous eligibility for adults, Montana state officials reported administrative savings and fewer staff hours needed to process individuals moving off and on the program.<sup>17</sup> Further, most metrics used to measure managed care performance as well as overall program performance (such as those in the Child Core Set) require that a beneficiary be enrolled for a minimum period of time to be included in the baseline.<sup>18</sup> Consequently, as beneficiaries churn off and on coverage, their experience is not reflected in the performance metrics. With Oregon's innovative continuous eligibility provisions in place, the measures would more fully reflect access and allow the state to incentivize and reward value more accurately in their managed care payment methodology.

In short, Oregon's proposal to test multi-year continuous eligibility period leads to promising programmatic hypotheses including increased access to preventive care, reduced health care costs in the long term, and lower administrative burden. A robust evaluation of such a groundbreaking policy will help advance knowledge about the ways to ensure that children and families—especially those of color—are best supported to grow and thrive. As showcased in their innovative kindergarten readiness metric, the state has already mapped out how to collect valuable data measuring the impact of improved access to social-emotional health services for young children. Oregon should also consider measuring service use and cost of care before and after the implementation. In future years, it could be illuminating for the state to study school attendance for children who had regular access to care through the continuous eligibility period.

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<sup>15</sup> Sara R. Collins, Munira Z. Gunja, and Gabriella N. Aboulaflia, "U.S. Health Insurance Coverage in 2020: A Looming Crisis in Affordability—Findings from the Commonwealth Fund Biennial Health Insurance Survey," The Commonwealth Fund, August 2020, [https://www.commonwealthfund.org/sites/default/files/2020-08/PDF\\_Collins\\_looming\\_crisis\\_affordability\\_biennial\\_2020\\_exhibits.pdf#page=6](https://www.commonwealthfund.org/sites/default/files/2020-08/PDF_Collins_looming_crisis_affordability_biennial_2020_exhibits.pdf#page=6); Matthew Rae *et al.*, "The Burden of Medical Debt in the United States," Kaiser Family Foundation, March 10, 2022, <https://www.kff.org/health-costs/issue-brief/the-burden-of-medical-debt-in-the-united-states/>.

<sup>16</sup> Jack P. Shonkoff, Natalie Slopen, David R. Williams, "Early Childhood Adversity, Toxic Stress, and the Impacts of Racism on the Foundations of Health," *Annual Review of Public Health* 42, no. 1, April 2021, <https://www.annualreviews.org/doi/abs/10.1146/annurev-publhealth-090419-101940>; Daniel Brisson, "A Systematic Review of the Association between Poverty and Biomarkers of Toxic Stress," *Journal of Evidence-Based Social Work* 17, no. 6, July 12, 2020, <https://www.tandfonline.com/doi/abs/10.1080/26408066.2020.1769786>.

<sup>17</sup> Niranjana Kowlessar *et al.*, "Federal Evaluation of Montana Health and Economic Livelihood Partnership (HELP): Summative Evaluation Report," Social & Scientific Systems and Urban Institute, November 30, 2020, <https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/summative-eval-rpt-montana-2020.pdf>.

<sup>18</sup> Center for Medicaid and CHIP Services, "Core Set of Children's Health Care Quality Measures for Medicaid and CHIP (Child Core Set) Technical Specifications and Resource Manual for Federal Fiscal Year 2021 Reporting," March 2021, <https://www.medicaid.gov/medicaid/quality-of-care/downloads/medicaid-and-chip-child-core-set-manual.pdf?t=1649430166>.

## **Dropping the request to waive retroactive eligibility restores a vital protection for beneficiaries.**

Oregon should be commended for dropping its request to waive retroactive eligibility. Retroactive coverage is an essential protection for low-income families, especially people of color who are more likely to have medical debt.<sup>19</sup> We are pleased Oregon has recognized that the outdated waiver was no longer experimental and indeed contrary to their stated goals of promoting health equity, maximizing coverage, and coordinating access to care. We urge other states to follow suit.

## **Extending coverage for children with special health care needs will promote health equity and maximize coverage.**

Currently, children with special health care needs whose families earn 300 percent of the Federal Poverty Level or less are eligible for OHP coverage. About 43 percent of children with special health care needs in Oregon receive coverage through OHP.<sup>20</sup> Oregon proposes to extend this coverage at the current eligibility level through age 26 and provide enhanced services to help individuals transition from pediatric to adult care. This proposal serves the objectives of Medicaid and has a valid experimental purpose. *We encourage CMS to approve the extension of coverage to children with special health care needs through age 26.*

Maintaining the enhanced eligibility level will likely increase the share of these youth who have continuous access to care. This initiative would also align coverage with the American Academy of Pediatrics' Bright Futures guidelines which describe the "flexible process" of moving from pediatric to adult care as culminating in the mid-20s.<sup>21</sup> In turn, the transition services could help increase access to appropriate supports, thus improving outcomes and promoting health equity for the special health care needs community. An evaluation of the program would illuminate best practices for transitioning from pediatric to adult care.

## **Removal of the EPSDT waiver is a vital improvement, but the continued use of the prioritized list is inconsistent with the EPSDT benefit and raises serious concerns about access to services going forward.**

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit is the cornerstone of children's coverage in Medicaid which guarantees that children and young

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<sup>19</sup> Leonardo Cuello, "Retroactive Coverage Waivers: Coverage Lost and Nothing Learned," Georgetown University Center for Children and Families Say Ahh! Health Policy Blog, October 4, 2021, <https://ccf.georgetown.edu/2021/10/04/retroactive-coverage-waivers-coverage-lost-and-nothing-learned/>; Matthew Rae *et al.*, Op cit.

<sup>20</sup> Elizabeth Williams and MaryBeth Musumeci, "Children with Special Health Care Needs: Coverage, Affordability, and HCBS Access," Kaiser Family Foundation, October 4, 2021, <https://www.kff.org/report-section/children-with-special-health-care-needs-coverage-affordability-and-hcbs-access-appendix/>.

<sup>21</sup> Joseph F. Hagen, Judith S. Shaw, and Paula M. Duncan, eds., "Promoting Health for Children and Youth with Special Health Care Needs," in *Bright Futures Guidelines* [Pocket Guide], 4<sup>th</sup> ed., American Academy of Pediatrics, February 2017, [https://brightfutures.aap.org/Bright%20Futures%20Documents/BF4\\_CYSHCNHealth.pdf](https://brightfutures.aap.org/Bright%20Futures%20Documents/BF4_CYSHCNHealth.pdf).

adults under age 21 receive the full scope of services necessary for their healthy growth and development.<sup>22</sup> Oregon has waived the EPSDT benefit for children since the inception of their demonstration in 1994, allowing them to limit children’s services to those included on a “prioritized list” determined by the governor-appointed Health Evidence Review Commission (HERC). As of August 2021, there were over 460,000 children enrolled in Medicaid in Oregon.<sup>23</sup>

In its application, the state makes the welcome proposal to phase out its waiver of EPSDT. This is a critical step towards ensuring that children in Oregon have access to the services to which they are entitled. The state suggests that during a transition period ending no later than January 2024, the HERC will undertake a review of services not currently covered and revise the list such that all medically necessary pediatric services are “above the line” (covered). Once the revision is complete, the state promises that any service indicated by an EPSDT screen which is not included on the list will receive an individualized medical necessity review. It should be noted that it is difficult to comment on the state’s application given the lack of detail, including the absence of any concrete information about the proposed individualized medical necessity review process to access EPSDT services. While we applaud the state’s decision to drop its request for a waiver of EPSDT, we believe the state’s proposal to continue using the prioritized list is incompatible with the basic purpose and design of the EPSDT benefit and does not serve the objectives of Medicaid.

The “treatment” portion of EPSDT guarantees children access to all medically necessary services, even if they are not covered by the state plan.<sup>24</sup> As CMS explains in their guide to EPSDT, the determination of medical necessity is made for an individual child, “taking into account the *particular* needs of the child.”<sup>25</sup> The state’s proposal to revise the prioritized list such that “all medically necessary EPSDT services for the population of children and adolescents are covered” glosses over the fact that medical necessity is an individual (as opposed to a population) standard. Full EPSDT access is of particular importance 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.<sup>26</sup> The HERC may place *common* pediatric services on the list, however there is no way to fully capture what providers will deem necessary for individual children. Consequently, the list will always be a subset of possible EPSDT services and act as a barrier to care.

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<sup>22</sup> Title XIX of the Social Security Act, §1905(r).

<sup>23</sup> Centers for Medicaid & Medicare Services, “State Medicaid and CHIP Applications, Eligibility Determinations, and Enrollment Data,” March 28, 2022, <https://data.medicaid.gov/dataset/6165f45b-ca93-5bb5-9d06-db29c692a360/data>.

<sup>24</sup> Title XIX of the Social Security Act, §1905(r).

<sup>25</sup> Emphasis added. Centers for Medicaid & Medicare Services, “EPSDT – A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents,” June 2014, [https://www.medicaid.gov/sites/default/files/2019-12/epsdt\\_coverage\\_guide.pdf](https://www.medicaid.gov/sites/default/files/2019-12/epsdt_coverage_guide.pdf).

<sup>26</sup> 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>.

Additionally, a list without a defined benefit or “floor” creates uncertainty about what and how services will be covered in the future. The list and “coverage line” can be revised frequently and services once covered—including state plan services—can be moved “below the line.” Consequently, there is no guarantee that the list will not be revised in the future to cover fewer pediatric services should there be an economic crisis, change in state government, or some other circumstance. CMS should also consider how such an “EPSDT list” might set a precedent for other state and federal administrations that are hostile to EPSDT. Ultimately, Congress has set out a defined Medicaid benefit in law, and it is not within the power of states, CMS, or section 1115 authority to alter that design.

Further, the continued use of the list does not serve an experimental purpose. The only hypothesis that comes from the continued use of the list is the extent to which it restricts access to necessary services. However, even this will not be tested given that the list does not appear anywhere in the state’s proposed evaluation design. In any case, Oregon has used a list for almost three decades and the experiment should be complete. Without a legitimate experimental purpose, there is also no basis to approve an 1115 waiver.

We also have significant concerns about the proposed implementation of this policy, based on the details we can garner from the application. First, the state outlines a “transition period” to phase out its waiver of the EPSDT benefit by January 1, 2024, yet it is unclear what policy applies during and after the transition period. Will children still be subject to the prioritized list? Will there be an appeals process through the state agency? How will the proper provision of services be monitored across CCOs? How will the state ensure that there is a strong public outreach process which meets the standard of section 1902(a)(43) of the Social Security Act? If CMS allows this lengthy-phase down process, it should require the state to adopt mitigation and monitoring strategies including communication strategies and grievance/appeal reviews. No child should have reduced access to services during the transition period.

In practical terms, the continued use of a list for children, even if there is an exceptions process, in parallel to the use of an *exclusionary* list for adults will cause confusion for enrollees and providers and create a de facto waiver of EPSDT. The application includes no explanation of the individualized medical necessity review process that will occur during and after the proposed “transition period,” although the state does admit that “these processes can be lengthy and burdensome to providers and families.” Nor does the application include adequate information about outreach or education to ensure that providers and families are informed of the right to such a review. The state also does not detail how such restrictions on and confusion around EPSDT services will impact children of color. As recognized by the Biden Administration, administrative burden has a disproportionate impact on families of color.<sup>27</sup> *Imposing additional burdens on families is contrary to the demonstration’s stated goal of achieving health equity and CMS’s strategic vision promising to link new initiatives to progress on reducing health disparities.*<sup>28</sup>

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<sup>27</sup> Office of Management and Budget, “Study to Identify Methods to Assess Equity: Report to the President,” July 20, 2021, <https://www.whitehouse.gov/wp-content/uploads/2021/08/OMB-Report-on-E013985-Implementation-508-Compliant-Secure-v1.1.pdf#page=21>.

<sup>28</sup> Chiquita Brooks-LaSure and Daniel Tsai, Op cit.

There is no clear purpose to continue using the list for children, but there is clear harm. *Our recommendation is that CMS deny the continued use of any extra list for children, regardless of the exceptions process.* However, if, contrary to our suggestion, CMS allows the continued use of a list, it is imperative that CMS require the state to publicly explain and implement a strong outreach and exceptions process plan. CMS must ensure the state, at a minimum, does the following:

- creates a publicized and accessible exceptions process (with readable forms, information available to providers, translation services readily available);
- does not create lists, limits, or prior authorization guidelines that cause delays for screenings (both periodic and nonperiodic);
- imposes only soft/flexible utilization management limits;
- establishes clear guidelines for out-of-network providers, use of one-time service arrangements, and overriding billing code issues;
- engages in continual oversight of CCOs and providers including reviews of utilization and grievances/appeals;
- and provides outreach to patients (including parents who may themselves be subject to an exclusionary list) and provides training to CCOs and providers (who will have other adult patients also subject to exclusionary lists).

### **Significant investments in social drivers of health will improve outcomes and promote equity but raise questions about standardization and oversight.**

Oregon proposes to deepen its standing commitment to addressing social drivers of health (SDOH) in two main ways. First, in addition to the existing health-related “flexible” services offered by CCOs, Oregon proposes to offer a defined set of “SDOH services” for individuals experiencing life transitions or extreme vulnerability. Additionally, as directed by Oregon House Bill 3353, the state proposes to require CCOs to spend three percent of their base budget for population health on health equity initiatives. While we applaud the state for its attention to social drivers of health and health equity, *we recommend CMS ensure that health-related services and investments are subject to the same level of oversight as traditional state plan services.*

First, given that the state plans to significantly increase investment in these health-related services, we believe it is only equitable if there is a base level of standardization of benefits across CCOs. Currently, CMS places some protections on non-medical spending. When MCOs offer “value-added” services that vary between organizations, they are counted towards the MCOs’ administrative expenses and consequently often limited in scope.<sup>29</sup> And, when states give MCOs the option to cover “in-lieu of services” (ILOSes), beneficiaries must maintain access to the traditional state plan services ensuring a base level of equality across MCOs.<sup>30</sup> Although increasing the health-related services beneficiaries can receive has the potential to reduce health inequities, if there are vast differences between what CCOs offer, it could *increase inequities*. If, as Oregon proposes,

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<sup>29</sup> 42 CFR 438.3(e)(1).

<sup>30</sup> 42 CFR 438.3(e)(2).

health-related benefits are to make up a significant part of CCOs' budgets, are counted with medical services in the numerator of the medical loss ratio (MLR) and in the rate-setting process (discussed further below), they should be subject to the same guidelines as medical services. That is, there should be standardization of and transparency about which health-related services enrollees will have access to. Additionally, while the proposed transition services are designed as a standard set of benefits across all CCOs, it is important that access to these services is administered in an equitable way. Will the state or the CCOs determine eligibility for the transition packages? If it is the CCOs, will there be a standard screening tool across all of the organizations? How will Medicaid enrollees and providers will know what services are available?

Second, if CCOs are to increase their health-related services spending and implement the transition-related services, it is vital that beneficiaries have access to due process, just as they do for state plan services. Strong guardrails are particularly important given that Oregon's CCOs have faced challenges respecting member rights and protections in the past. In the state's 2020 External Quality Review Organization report, the reviewers wrote:

Member Rights and Protections represented the greatest struggle for all CCOs [...] many of the CCOs were non-compliant with the State requirement to offer members all options for reporting a discrimination complaint. In addition, several CCOs did not provide evidence of implementing community education on advance directives as required by the state. The [compliance monitoring reviews] raised concerns with regard to CCO oversight of delegates around ensuring appropriate oversight and consistent delivery of benefits within and across CCOs.<sup>31</sup>

In order to make sure that all enrollees who would benefit from HRS can access the services, there must be a system for them to submit complaints and challenge inappropriate denials. Further, we recommend that CMS require the EQRO to assess and report on access to HRS and transition benefits, as well as due process procedures, on a CCO-specific basis.

Finally, if approved, the state should be required to conduct a robust evaluation of the HRS and the transition services. The state should identify what HRS services were provided to what populations, in what amount, duration, and scope, and this information should be broken down and publicly available. To the extent possible, the impact of each individual HRS and transition benefit package should be studied, again disaggregated by CCO, so that it is clear which services and investments increase access to valuable care.

### **Expanded peer-delivered services (PDS) will help address health inequities and expand access to care.**

As part of its SDOH and health equity strategy, Oregon also proposes to expand access to peer-delivered services (PDS) by removing requirements for clinical supervision and treatment plans as a condition of reimbursement. In addition to the existing state plan PDS

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<sup>31</sup> Health Services Advisory Group, "2020 External Quality Review Technical Report," April 2021, pg. 1-2, [https://www.oregon.gov/oha/HSD/OHP/DataReportsDocs/OR2020\\_EQR%20Technical%20Report\\_F2.pdf](https://www.oregon.gov/oha/HSD/OHP/DataReportsDocs/OR2020_EQR%20Technical%20Report_F2.pdf).

which reimburse workers as part of a treatment, this change will allow individuals to benefit from culturally competent support in less structured circumstances, including recovery. Traditional health workers such as community health workers and doulas who share a background with the community they serve have the potential to connect individuals to the health system and address health inequities.<sup>32</sup> Oregon should be commended for its intent to remove the barriers to compensation for traditional health workers, and *we urge CMS to approve this provision*. A strong evaluation of PDS utilization and access to care will prove useful to other state Medicaid programs thinking through how to sustainably support traditional and community health workers.

**The requested managed care flexibilities are too broad and have the potential to harm access.**

As described above, the state proposes to add several new features to their ongoing efforts to provide “health-related services” and address social drivers of health. While we are supportive of the intent to expand these services targeted at health-related social needs, we are concerned that the authorities the state is requesting circumvent several key managed care guardrails.

Section 1115 does not authorize CMS to waive provisions of sections 1903 or 1932 of the Social Security Act or the related managed care regulations at 42 C.F.R. §438, including the rate development standards set out in 42 C.F.R. §438.5. However, Oregon is requesting expenditure authority to “pay for capitation rates that are built with specified deviations from the rate development standards outlined in 42 C.F.R. §438.5.” Section 1903(m)(2)(A)(iii) of the Social Security Act mandates that managed care entities be compensated “on an actuarially sound basis.” The state proposes to rebase its capitation rates every five years and proposes to limit the growth of their capitation rates to 3.0 to 3.4 percent annually—practices that are well outside of the professional standards of actuarial soundness. Such policies could lead to capitation payments to MCOs that are not actuarially sound, especially when, as here, the state is significantly increasing the workload of the CCOs. *CMS should not approve any waiver or expenditure authority that has obvious potential to violate actuarial soundness, should clarify that any rate-setting waivers do not include waivers of actuarial soundness, and should develop guardrails to ensure that Oregon’s CCO payments remain actuarially sound at all times.*

We are concerned about the compounded impact of continuing to increase coverage of new health-related services (which in itself is a laudable goal) while *at the same time* imposing an artificial cap on rates. Such an arrangement, stripped of the guardrails of

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<sup>32</sup> Sonali Saluja *et al.*, “Community-Based Health Care Navigation’s Impact on Access to Primary Care for Low-Income Latinos,” *Journal of the American Board of Family Medicine* 35, no. 1, January/February 2022, <https://www.jabfm.org/content/35/1/44>; Michele Heisler *et al.*, “Impact on Health Care Utilization and Costs of a Medicaid Community Health Worker Program in Detroit, 2018-2020: A Randomized Program Evaluation,” *American Journal of Public Health*, online ed., March 24, 2022, <https://ajph.aphapublications.org/doi/10.2105/AJPH.2021.306700>; James Krieger *et al.*, “The Seattle-King County Healthy Homes II Project: A Randomized Controlled Trial of Asthma Self-management Support Comparing Clinic-Based Nurses and In-Home Community Health Workers,” *The Archives of Pediatrics & Adolescent Medicine* 163, no. 2, 2009, <https://jamanetwork.com.proxy.library.georgetown.edu/journals/jamapediatrics/fullarticle/380846>.

actuarial soundness, could lead to financial instability for Oregon’s coordinated care organizations (CCOs) and harm beneficiary access. CCOs may be forced to cut expenses, increase utilization management, narrow networks, and lower provider compensation—all of which could inhibit access to needed medical services. The financial instability could also lead to some CCOs failing, which would necessitate mass transitions that always result in care disruptions. In the alternative, CCOs might simply choose to remain solvent by ignoring the new set of health-related services, meaning the whole effort is for naught. These outcomes do not promote the objectives of the Medicaid program.

In order to reap the benefit of the enhanced flexible and transition services, CCOs must be compensated appropriately. It is unrealistic for the state to believe that investments in health-related social needs will lead to equivalent and instantaneous savings on traditional state plan services. Some investments will take decades to pay off, while others may not succeed at all. According to the state’s budget neutrality analysis, the waiver will result in over \$16 billion in savings by 2027—meaning that the state does not need a self-imposed cap to meet budget neutrality. We recommend the state develop rates based on all required state plan services *and* supplement those rates by adding health-related services in accordance with recommendations from their actuaries. Over time, effective investments will likely lead to state plan service reductions as outcomes improve and need declines, however this transition cannot be forced by over-zealous timelines and budgets.

Oregon also requests to continue their waiver to allow CCOs to treat health-related services (HRS) like medical expenditures for purposes of calculating the medical loss ratio (MLR) and requests new authority to count health equity investments as medical expenses in the rate-setting process. We are supportive of the state’s goal to facilitate the coverage of HRS by allowing these services to be fully integrated into the Medicaid services package, including for rate-setting. At the same time, one of the findings of the interim evaluation of the 2017-2022 demonstration is that spending on HRS seemed to vary between CCOs given confusion over what qualifies as HRS. As noted above, oversight is needed to ensure that CCOs offer similar and consistent access to HRS. Additionally, it is critical that the state ensures CCOs do not characterize routine administrative spending as HRS to inflate their MLR or rate-setting baselines. While the application suggests that this spending is broken out for CMS review in the rate-setting process, it is important that there is public transparency and accountability about how CCOs are compensated and what they are spending on HRS. *We recommend the state be required to publicly list all HRS that are counted towards the medical load and share the disaggregated MLR reporting.*

Oregon continues to request to limit choice of managed care plan and disenrollment, as well as mandatorily enroll populations that are protected by the statute, including dual eligibles. While the state waiver list cites sections 1902(a)(23) and 1902(a)(4) of the Social Security Act, the requirements being waived are found and independently required by sections 1932 and 1903. For example, section 1932(a)(2) prohibits mandatory enrollment of certain children with special needs, dual eligibles, and Native Americans. Sections 1932 and 1903 are not waivable under section 1115. In addition, the state has offered no explanation as to why these waivers would be *necessary* to the operation of its demonstration.

## **The use of the prioritized list for adults limits access to care and no longer promotes the objectives of Medicaid or serves an experimental purpose.**

While we are pleased that the state has recognized that an exclusionary list of services is detrimental to children, we are disturbed by the state's request to continue limiting access to services for adult beneficiaries through the prioritized list. The Oregon State Legislature first mandated the creation of the list in 1989 as a means of conserving fiscal resources when the state expanded coverage to low-income individuals at or below 100 percent of the federal poverty level (FPL).<sup>33</sup> At the time, this population was not included in Title XIX of the Social Security Act and not eligible for federal matching funds. Consequently, the waiver of requirements around state plan benefits arguably met the objectives of Medicaid—to provide coverage—and may have been a budgetary necessity. CMS approved the state's request for a waiver in 1993 and the state began to limit health and dental services for all OHP members according to list in 1994.<sup>34</sup>

However, twelve years after the enactment of the Affordable Care Act there is no reason to continue limiting access to services for any population, nor does it appear permissible. Individuals under 138 percent of the federal poverty level are now incorporated in the statute as the “new adult population”— they are no longer a classic expansion population.<sup>35</sup> As such, a demonstration offering a limited set of services does not add to their care, but rather reduces coverage for all eligibility groups. Consequently, such a waiver is no longer consistent with the objectives of Medicaid. Further, rationing care is no longer a financial necessity. The new adult group receives a generous 90 percent federal match. And, the demonstration's net cumulative variance from current and prior waiver periods of over \$16 billion makes clear that Oregon does not need to restrict coverage to meet budget neutrality requirements. The waiver has simply become a tool for fiscal control for the state legislature, and allowing the state to pull down enhanced federal funds while offering limited services relative to other states and federal requirements. Congress never intended the Oregon state legislature to supplant its role in defining the required Medicaid benefit.

The state's application also does not include any measurement of the prioritized list's impact on beneficiaries in their proposed evaluation. What required services will adults lose access to and what harms will that cause? What impact does the exclusionary list have on vulnerable populations such as pregnant women? Does the prioritized list exacerbate racial and ethnic health disparities? This demonstration raises serious concerns while lacking a useful or promising hypothesis. Given that the prioritized list limits access to coverage, does not promote the objectives of Medicaid, and no longer serves an experimental purpose, *we strongly believe that the state should be required to provide all mandatory Medicaid services for all populations.*

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<sup>33</sup> Oregon Health Authority, “Prioritized List Overview,” <https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Prioritized-List-Overview.aspx>.

<sup>34</sup> Ibid.

<sup>35</sup> P.L. 111-148 (2010)

**Oregon’s request for authority to exclude certain accelerated approval drugs could restrict beneficiary access to needed prescription drugs and is not an appropriate use of section 1115 authority.**

Oregon seeks the authority to exclude from coverage drugs that have been approved through the Food and Drug Administration’s (FDA) “accelerated approval” pathway which the state deems to have “limited or inadequate evidence of clinical efficacy.” Accelerated approval by the FDA allows drugs to come to market based on surrogate endpoints that are reasonably likely to predict clinical benefits even though clinical benefits themselves have not yet been demonstrated.<sup>36</sup> Manufacturers who do not complete confirmatory trials within an FDA-approved timeline can have their drug withdrawn from the market.<sup>37</sup> The accelerated approval pathway has allowed timely access to many cancer drugs, for example.<sup>38</sup> However, there are well-acknowledged problems with FDA’s accelerated approval process. For example, some drug manufacturers never complete required post-market confirmatory clinical trials or do so only after long delays. Some do not convert their drugs to traditional FDA approval for many years, if at all.<sup>39</sup> While we acknowledge the state’s concerns with the accelerated approval pathway and the resulting budgetary impact on the Medicaid program, we have serious concerns that such a policy would restrict access for beneficiaries to newer, high-cost prescription drugs that they need and set an untenable, highly troubling precedent. Consequently, *we urge CMS to reject Oregon’s request. Far better alternatives would be for Congress to enact reforms to the FDA accelerated approval itself to ensure that manufacturers complete their confirmatory trials on a timely basis and convert to traditional FDA approval. CMS could also work with Congress to strengthen the Medicaid Drug Rebate Program (MDRP) which could encourage manufacturers to complete their confirmatory trials, as recommended by the Medicaid and CHIP Payment and Access Commission (MACPAC).*

Medicaid’s open-formulary requirement serves as an essential protection for low-income beneficiaries and is an integral part of the Medicaid Drug Rebate Program (MDRP). If Oregon was granted the authority to eliminate the open-formulary protection, it could inhibit access to new and promising drugs for serious conditions like cancer. Despite the risks to beneficiaries the proposal poses, the application leaves many questions unanswered.

The state proposes to undertake “its own rigorous review” of the clinical research, yet, concerningly, provides no detail on which drugs would be subject to this review. It could encompass all accelerated-approval drugs that have not yet converted to traditional FDA

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<sup>36</sup> U.S. Food and Drug Administration, “Accelerated Approval,” January 4, 2018, <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/accelerated-approval>.

<sup>37</sup> Ibid.

<sup>38</sup> Eva Temkin and Jonathan Trinh, “FDA’s Accelerated Approval Pathway: A Rare Disease Perspective,” National Organization for Rare Disorders, June 2021, <https://rarediseases.org/wp-content/uploads/2021/06/NRD-2182-Policy-Report-Accelerated-Approval-FNL.pdf>.

<sup>39</sup> Elizabeth Mahase, “FDA Allows Drugs without Proven Clinical Benefit to Languish for Years on Accelerated Pathway,” *The BMJ* 374, July 30, 2021, <https://www.bmj.com/content/374/bmj.n1898.short>.

approval, which would be the majority of drugs approved within the last five years.<sup>40</sup> Or it could only include drugs that have not completed confirmatory clinical trials within the FDA timelines set in the original approval. The state also does not define “limited or inadequate evidence of clinical efficacy.” The only assurance the state offers is that the review would be based on the timelines outlined in the original FDA approval letter and on a synthesis of peer-reviewed literature. An appendix in the waiver application, however, indicates most or all accelerated-approval drugs that have not converted to traditional approval could be defined as having limited or inadequate clinical efficacy. This means that the state could exclude many accelerated-approval drugs. The proposal also does not describe what body will be responsible for deciding which drugs are excluded from coverage and how the state will ensure that they have adequate clinical expertise. In addition, the state does not include an exceptions process, information on how beneficiaries can appeal a decision and the criteria that would be used to review an appeal (nor, indeed, how the limitations interact with the use of the prioritized list or the removal of their EPSDT waiver). Finally, the application includes no details about how the proposal to limit access would serve the demonstration’s goal of furthering health equity, nor any analysis of how the provision would impact vulnerable populations, including people with life-threatening diseases, chronic conditions, and disabilities.

While we understand the need for the state to slow the growth in Medicaid prescription drug costs—although accelerated approval drugs constitute only about four percent of net Medicaid drug spending—section 1115 policy is not the venue to address this issue.<sup>41</sup> The open formulary requirement is critical to the operation of the MDRP, which ensures that Medicaid has the lowest drug prices, net of rebates and discounts, of federal programs and agencies.<sup>42</sup> The state is seeking the authority to exclude these prescription drugs by waiving the requirement in section 1902(a)(54) of the Social Security Act to follow section 1927, which includes the open formulary protection. CMS has previously disapproved this end-run around the guardrail that only section 1902 is waivable and maintained that participating in the MDRP requires following all provisions of section 1927.<sup>43</sup> *We strongly recommend that CMS maintain this precedent and reject the state’s request to limit access to accelerated approval drugs.* CMS should instead work with lawmakers to require a higher rebate from manufacturers for accelerated approval drugs until confirmatory trials are completed (as MACPAC recommends) and empower the FDA to institute more guardrails and enforcement related to the accelerated approval pathway.<sup>44</sup>

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<sup>40</sup> Food and Drug Administration, “CDER Drug and Biologic Accelerated Approvals Based on a Surrogate Endpoint as of December 31, 2021,” January 2022, <https://www.fda.gov/media/151146/download>.

<sup>41</sup> Benjamin Rome and Aaron S. Kesselheim, “Raising Medicaid Rebates for Drugs with Accelerated Approval,” *Health Affairs* 40, no. 12, December 2021, <https://www.healthaffairs.org/doi/10.1377/hlthaff.2021.00762>.

<sup>42</sup> “A Comparison of Brand-Name Drug Prices Among Selected Federal Programs,” Congressional Budget Office, February 18, 2021, <https://www.cbo.gov/publication/56978>.

<sup>43</sup> “MassHealth Demonstration Amendment Approval,” Centers for Medicaid and Medicare Services, June 27, 2018, <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ma/MassHealth/ma-masshealth-demo-amndmnt-appvl-jun-2018.pdf#page=2>.

<sup>44</sup> Medicaid and CHIP Payment and Access Commission, “Addressing High-Cost Specialty Drugs,” June 2021, <https://www.macpac.gov/publication/addressing-high-cost-specialty-drugs/>

## Conclusion

Our comments include numerous citations to supporting research, including direct links to the research, for HHS's benefit in reviewing our comments. We direct HHS to each of the studies cited and made available to the agency through active hyperlinks, and we request that the full text of each of the studies cited, along with the full text of our comments, be considered part of the administrative record in this matter for purposes of the Administrative Procedure Act.

Thank you for consideration of our comments. If you would like any additional information, please contact Joan Alker ([jca25@georgetown.edu](mailto:jca25@georgetown.edu)) or Leo Cuello ([lc1247@georgetown.edu](mailto:lc1247@georgetown.edu)).

Respectfully,

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