April 13, 2022

VIA ELECTRONIC SUBMISSION

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,

The undersigned organizations appreciate the opportunity to comment on Oregon’s renewal application for the “Oregon Health Plan” section 1115 demonstration. Section 1115(a) of the Social Security Act gives the Secretary authority 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).1 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).2 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, other provisions—such as the limitations on EPSDT as well as accelerated approval drugs—would limit access to care and do not meet the objectives of the Medicaid. 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 and limit administrative burdens 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 exactly the type of proposal for which 1115 demonstrations should be used; there is much to be learned from this approach. We strongly urge CMS to approve Oregon’s 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 Dan Tsai, lengthening continuous eligibility for children and adults has the potential to remedy disparities in coverage. 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. Continuous eligibility can help mitigate the disproportionate impact of churn and uninsurance. From 2019 to 2021, while the continuous eligibility provision in the Families First Coronavirus Response Act (FFRCA) was in effect, the coverage disparity between Black Oregonians and white Oregonians narrowed as Black Oregonians saw the largest percentage point decline in their uninsured rate of any race/ethnicity. While this decrease in uninsurance may be the result of multiple factors, the FFRCA continuous eligibility provision, which is estimated to be preserving enrollment for about 13 million people as of early 2022, was likely a major factor.

Continual access to care is vital for the healthy development of young children. Children with unaddressed conditions such as asthma, vision, hearing impairment, nutritional deficiencies, and mental health challenges are unable to thrive in kindergarten and beyond. 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. 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.

For older children and adults, continuous eligibility can also also improve health outcomes by ensuring timely access to care. People who experience disruptions in coverage are more likely to

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


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.\(^\text{11}\)

Finally, continuous eligibility has the potential to free up administrative resources, improve program efficiency, and reduce burdens on families. 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.\(^\text{12}\)

Extending continuous eligibility has a valid and commendable experimental purpose that serves the objectives of the Medicaid program. When evaluating the extension, Oregon should consider disaggregating all metrics by race and ethnicity to the extent possible and measuring service use and cost of care before and after the implementation.

Oregon should also be commended for dropping its request to waive retroactive eligibility. Retroactive coverage is an essential protection for low-income people, especially people of color who are more likely to have medical debt.\(^\text{13}\) We are pleased Oregon has recognized that the outdated waiver was no longer experimental and indeed contrary to their stated goals of health equity, maximizing coverage, and coordinating access to care.

**Oregon should establish standards and processes to ensure equitable distribution of social determinants of health (SDOH) transition services.**

Oregon’s demonstration proposal would provide enrollees who are experiencing certain transitions a “defined set of SDOH transitional services.” Initially, these services would be funded through expenditure authority outside of Coordinated Care Organization (CCO) capitated payments. Oregon is also requesting up-front federal funds to expand the infrastructure needed to support the provision of these services.

Focusing on groups experiencing transitions to demonstrate whether providing services such as non-medical transportation, food assistance, and housing supports has an impact on their health outcomes and health costs could be an appropriate use of demonstration authority, as we explain below. But to ensure that it promotes Medicaid’s objectives, distribution of these services must be

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fair and equitable. CMS should require that Oregon provide due process protections to enrollees and establish processes to monitor and hold CCOs accountable for how they provide these services.

The proposal includes minimal details on how SDOH Transition Services would be provided, stating only that once a member is “deemed eligible” based on their transition, “a social needs screening assessment will be used to identify which benefits are relevant.” There are two points where due process needs to be taken into account: (1) the determination of eligibility based on the transition; (2) the determination of benefits that will be provided.

We understand the need for flexibility in providing these services so that they can be tailored to meet an individual’s needs, but that does not eliminate the need for clear standards and transparency, particularly when administration of the services will be spread across multiple CCOs. Some of the definitions are clearer than others. For example, it’s clear when an enrollee is transitioning from Medicaid to Medicare-Medicaid coverage or when youth are aging out of foster care. But it’s not clear how CCOs would determine whether an enrollee is “vulnerable to extreme weather events.”

For those determined eligible for transition services, CMS should require more details on the social needs assessment, how it will be administered, and how eligibility for particular transition services will be determined. Specifically, will it be standard across all the groups experiencing transitions or specific to the transitions? Will there be eligibility criteria tied to specific benefits? And will there be limits on the numbers of people who can receive benefits, or will all who meet the eligibility criteria receive the transition services?

Oregon should also provide more detail on the enrollee experience, particularly as to the application and eligibility determination process for transition services, the timing and types of notices enrollees will receive, and grievance and appeal rights.

**Providing services to meet social needs during transitions will reduce health inequities and improve health outcomes.**

Oregon proposes to provide new benefits to meet certain social needs including housing, food, transportation, education, employment, and climate disaster-related needs on a short-term basis. In order to be assessed for eligibility, people must be in detention, an IMD, a youth with special health care needs, or experiencing a transition that puts them at risk for disruption in care (such as involvement with the juvenile justice or child welfare systems, transitioning to dual enrollment, homelessness, or vulnerability to extreme climate events).

We are broadly supportive of the objectives of this proposed effort and agree that meeting people’s social needs by connecting them to services and supports can reduce health inequities, improve health outcomes, and may result in cost savings in some circumstances. Our specific comments focus on the proposed housing-related services.

**Housing-related supports.** Oregon proposes to offer housing-related supports to certain of the populations listed above, including adults in jails, prisons, and IMDs who are transitioning to the community, youth involved in or at risk of involvement in the juvenile justice and/or child welfare systems, people dually eligible for Medicaid and Medicare, and people experiencing or at risk of experiencing homelessness. The CCO would identify people in these groups and direct them to
complete a social needs assessment. People identified to have housing needs would gain access to housing-related supports such as home-and community-based services, utility assistance, pre-tenancy and tenancy sustaining services, housing-focused navigation, help finding and applying for suitable housing, and financial literacy and independent living skills-related supports. Medicaid can play a critical role connecting people to these kinds of housing-related supports and making these services available could increase access to supportive housing, an evidence-based solution to homelessness that can reduce utilization of preventable emergency services, improve access to appropriate health care services, and in some cases reduce health care expenditures.\footnote{Hannah Katch, “Medicaid Can Partner With Housing Providers and Others to Address Enrollees’ Social Needs,” CBPP, January 27, 2020, \url{https://www.cbpp.org/research/health/medicaid-can-partner-with-housing-providers-and-others-to-address-enrollees-social}.}

**Recommendations:**

- **Definition of homeless:** CMS should request additional information about how the state will define the population of people who are eligible for transition services due to experiencing or being at risk of experiencing homelessness. Medicaid and homelessness Continuums of Care should use consistent definitions of homelessness and at risk of homelessness to align eligibility for tenancy supports with eligibility for HUD-funded housing assistance. We recommend adopting a definition of “at risk of homelessness” that includes people living with another family or in crowded or substandard housing. This would help ensure the services are more inclusive of residents for whom housing instability often does not present in the form of sleeping in shelters or on the streets, for example AI/AN people and people living in rural areas.

- **Duration of eligibility for services:** CMS should request additional information on how long the “short-term” services will be available. For some individuals, providing services for a short period as the individual is transitioning from an institution to the community is appropriate. For others, particularly people with physical disabilities or complex mental health needs or substance use disorders, providing housing-related services on an ongoing basis may be needed to ensure the person can remain stably housed.

- **Prohibition on covering room and board:** Oregon’s proposal for temporary housing is too broad as currently proposed. Rental assistance is a proven strategy for providing stable, affordable housing for low-income people, but three-quarters of low-income renters who need assistance do not receive any because of limited federal funding.\footnote{“3 in 4 Low-Income Renters Needing Rental Assistance Do Not Receive It,” Center on Budget and Policy Priorities, July 2021, \url{https://www.cbpp.org/research/housing/three-out-of-four-low-income-at-risk-renters-do-not-receive-federal-rental-assistance}.} Medicaid cannot fill these vast funding gaps. Allowing Medicaid funds to meet needs underfunded by other sectors would erode Medicaid’s core mission as a health care program, making it more difficult to improve access to needed health care services. While CMS has approved California to offer up to six months of short-term, post-hospitalization housing through its Medicaid program, Oregon provides minimal details on the length of time temporary housing would be provided nor does it restrict the benefit to people leaving the hospital.

- **Funding mechanism:** We agree that the state’s proposal to fund housing and other services to meet health-related social needs should initially be separate from CCO capitation payments. CCOs should have time to establish the systems and relationships with
community-based service providers needed to facilitate provision of these services and to identify which services are most appropriate for which people before they assume risk. There are gaps in what is known about effective housing-related interventions, and what Oregon learns during the three-year transition could provide valuable information to people in Oregon and to CMS and other state Medicaid agencies about the factors that contribute to effective referrals.

- **Demonstration vs. state plan authority:** We note that Oregon proposes to deliver housing-related services, including “home- and community-based services” to enrollees through this 1115 demonstration rather than the 1915(i) state plan option. State plan coverage is appropriate to provide these evidence-based services to certain populations and gives service providers the confidence they need to continue expanding access to eligible enrollees. We encourage CMS to work with Oregon and other states to prepare to transition these important services from demonstration projects to state plan coverage.

The requested managed care flexibilities need to be clarified and CMS must ensure compliance with core managed care standards.

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 waivers and design may lead to managed care instability. The state suggests that the funding for some of these programs will be gradually transitioned into the CCOs’ capitation rates. The state also requests 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.” It is unclear what this waiver authority refers to within a complex demonstration that has at least four other waiver or expenditure authority requests related to managed care rate-setting. We urge CMS to explicitly clarify in its approval that all payments to CCOs must be fully compliant with the actuarial soundness requirements set out in statute (including sections 1903 and 1905 of the Social Security Act) and the Part 438 regulations. Such requirements cannot be waived and it would not promote the objectives of Medicaid to authorize a state to not comply with them.

The waiver language described above may relate to the state’s proposal to rebase its capitation rates every five years and limit the capitation rate growth to 3.0 to 3.4 percent annually. While we recognize that the state has suggested it will adjust the cap in exigent circumstances and that the state’s intent may not be to waive actuarial soundness, we believe this policy could lead to rates that are not actuarially sound. 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 limiting rebasing and applying a cap on rates. Such an arrangement could lead to financial instability for Oregon’s coordinated care organizations (CCOs) and harm beneficiary access. Approved rates may be too low by the end of the five years in any number of scenarios including high medical inflation or a public health emergency necessitating more health-related services. CCOs could be forced to cut expenses, increase utilization management, narrow networks, and lower provider compensation—all of which could inhibit access to needed medical services. Financial instability could also lead to some CCOs failing, which would necessitate transitions that result in care disruptions.
Ultimately, we believe the state’s rate-setting must acknowledge that investing in health-related social needs—which we wholeheartedly support—may not lead to instantaneous reductions in medical care that the state uses to justify capping capitation rate growth. CMS should clarify that the state’s payments for medical care and investments, which we believe will generate long-term medical savings, must remain actuarially sound throughout.

**Benefits for people in institutional settings will support success transitions but require further refinement.**

We support Oregon’s goal of using Medicaid to provide OHP enrollees with the support they need for a “successful transition back to their community” following incarceration or residential psychiatric care in an IMD. We recommend CMS work with Oregon to refine its proposal to ensure the state’s proposed services achieve their worthy goals and promote the objectives of the Medicaid program.

*Pre-release services for adults in detention.* Oregon requests authority to cover (1) a limited benefit package for adults in prison and young adults in youth detention; and (2) full OHP benefits for all people in jail regardless of length of detention with the goal of strengthening continuity of care and addressing health disparities.

The state correctly notes that transitions out of jail and prison are critical periods in which gaps in coverage and care are common. As the state’s proposal explains, people in jail and prison have high rates of chronic physical and behavioral health conditions but often return home without adequate access to medications or care coordination.16 Once home, health care often falls by the wayside as people face competing demands, including securing housing, finding work, filling prescriptions, connecting with family, and fulfilling court-ordered obligations. Gaps in coverage and care contribute to a litany of poor health outcomes and compound the harmful effects of mass incarceration and the over policing of people of color, particularly for Black and Hispanic people.

We strongly support the state’s proposal to ensure CCO enrollment prior to release and the state’s goal of addressing barriers to care as people transition to community-based care, though additional details are needed to understand whether the proposal would have its intended impact. While the Medicaid statute generally prohibits federal match for health care services delivered in correctional facilities, Medicaid can play a limited but important role in ensuring that people who are incarcerated get the coverage and care they need when returning to the community. However, Medicaid coverage of services delivered during incarceration should not be used to merely shift the cost of correctional care services from county and state governments to the federal government, but should enhance access to care and improve the continuity of care as people transition to community-based care.

*Transition services for adults in prison and young adults in youth detention.* We strongly support the approach of covering a targeted set of services during the last 30-90 days of incarceration to facilitate continuity of care, which appears to be Oregon’s intent for adults in prison and young adults in youth detention. However, Oregon does not explain what “the limited benefit

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package within 90 days of release” includes aside from the proposed transition SDOH services. Earlier in its proposal, the state mentions care coordination and navigation, which would be appropriate services to provide pre-release. Oregon should provide more information about the nature of the services, who will deliver them, and how they will ensure continuity of care and connection to community-based providers.

**Coverage of full benefits for adults in jail.** We have significant concerns about the state’s proposal to cover “full OHP benefits” for all adults in jail who are eligible for Medicaid. Without more guardrails, Medicaid coverage could allow for the reimbursement of existing services delivered by jail health providers, shifting the cost of the status quo without improving care, coordination, or health outcomes. In order to ensure that the state’s proposal advances equity and the objectives of the Medicaid program, we recommend that CMS work with the state to:

- **Distinguish between people in jail pre-adjudication and those who have been adjudicated.** The state correctly points out that care transitions are made more difficult for people in jail, many of whom have short stays lasting days or weeks and experience significant uncertainty about their release dates. But this is primarily the case for those being held pre-adjudication. Therefore, we recommend Oregon apply the limited benefit package it proposes for people in prison (and young adults in youth detention) to those in jail who are serving a sentence and have more certainty about their release date.

- **Design a tailored set of benefits for people held pre-adjudication that would build on and not supplant the services already available to people held in jail, instead of covering “full OHP benefits.”** The state should focus on services that are most critical for ensuring continuity of care upon incarceration and reentry, such as medications, key mental health and substance use services, care coordination and navigation, and the proposed SDOH services. While it may be appropriate for these services to be more robust than transition services for people with clear release dates, they should be designed to increase access to services and not just shift costs for jails.

- **Maximize the use of community-based providers for Medicaid services delivered in jail.** One promising strategy the state could adopt is to use Medicaid to cover “in-reach” services where case managers, clinicians, or peer support professionals visit people in jail or prison to help them prepare to return home. In-reach services would help people maintain existing relationships with local providers and build new ones.

- **Develop a plan for ensuring services delivered during incarceration are high quality and reach enrollees with the greatest need.** Relatedly, we strongly support the state’s plan to partner with the existing OHA Community Partner Outreach Program and jail staff to help eligible people apply for OHP within days of entering jail. This will be key to ensuring any covered services are available to those who need them.

**Medicaid coverage during the duration of youth detention.** Oregon requests authority to provide full benefits to Medicaid eligible youth in county or local juvenile detention for the duration of their involvement. We strongly support the state’s objective of addressing health inequities among justice-involved youth. However, caution and diligence are required to ensure coverage of pre-release services improves access to health care, care transitions, and health outcomes, and otherwise advances the objectives of Medicaid. Otherwise, Medicaid funding could be used perpetuate the harm the juvenile carceral system causes, instead of ending it.
Incarcerating children and young adults can cause serious harm to youth who are separated from their family and community, including long-term adverse impacts on individuals’ physical and mental health. And as the state’s proposal notes, youth of color are consistently incarcerated and sentenced at higher rates than white youth—a disparity that persists as overall youth confinement is declining. Medicaid can play an important role in ending the incarceration of young people and supporting the healing of youth who were previously incarcerated, but only if used as part of a comprehensive approach to preventing the incarceration of children and young adults, mitigating the harm for those who are incarcerated, and ensuring access to comprehensive health and social services for those who were formerly incarcerated.

We recommend that CMS work with the state to modify its youth proposal to focus on services during the last 60-90 days of confinement—a critical period for preparing youth to transition to community-based care—instead of covering services for the duration of confinement (if longer than 60-90 days). This would help mitigate the risk that Medicaid coverage of services during confinement would displace community-based services for youth involved in the justice system or incentivize the use of longer-term detention, while still allowing the state to better coordinate coverage and services for OHP enrollees in the juvenile justice system. We also recommend that CMS work with the state to learn how it will operationalize its proposal, including by:

- **Articulating a comprehensive approach to leveraging Medicaid to serve justice-involved youth.** While the state is requesting authority to cover services delivered while youth are in confinement, the state should also explain how Medicaid is or will be used to support efforts to divert young OHP enrollees from entering the juvenile system. This could include covering and increasing access to community-based services and using community-based crisis response services to prevent unnecessary arrest and hospitalization. For example, Oregon was among 20 states that recently received planning grants to prepare to implement the community-based mobile crisis intervention services state plan option created by the American Rescue Plan Act.

- **Ensuring that the proposal reflects the experiences of justice-involved youth and the needs of the community.** We urge the state to meaningfully engage community advocates,

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providers, and justice-involved youth in an ongoing way to shape the design and implementation of its proposal.

- **Providing more detail about service delivery.** The state provides no information about how health and supportive services are delivered to youth currently, the gaps in those services, and how the proposal would expand upon those efforts. Oregon should provide more detail about how OHP-covered services will be used to strengthen or change current practices, and how it will ensure the quality and continuity of care delivered to OHP enrollees during their detention. For example, will the state utilize community-based health systems to deliver care for youth in confinement and avoid the use of for-profit providers? And how will the state ensure that youth will have appointments scheduled with community-based providers, a supply of any needed medication, and support with navigating the health care system upon their release?

**Benefits for people transitioning out of IMD psychiatric residential facilities.** Care coordination and supports to secure community-based housing and other SDOH-related resources can be critical to ensuring people leave IMDs as soon as clinically appropriate and have access to the community-based care and other supports they need to remain in the community. Without appropriate supports, people with serious mental illness often endure a harmful cycle of repeated hospitalization and institutionalization, diminishing their independence, health, and quality of life.

The state’s proposal briefly mentions that it is seeking authority to “provide limited OHP benefits and CCO enrolment and transition services upon release” for people in “the Oregon State Hospital and any other IMD psychiatric residential facilities.” But the state provides no detail about the nature of services to be covered, how the services will be delivered, and how those services differ from the care coordination the state already covers under its 1115 demonstration for individuals residing in IMDs. For instance, are any of the services intended to be delivered prior to discharge, or solely “upon release”? What would be included in the “limited OHP benefits” package?

While coverage of a limited set of carefully tailored transition services—such as care coordination and SDOH transition services—may be appropriate during the final weeks of an IMD stay to ensure people return to the community as soon as possible, significantly more information is needed to ensure Oregon’s proposal would achieve that end. In contrast, coverage of a broad range of benefits during an IMD psychiatric residential stay that are not tailored to supporting care transitions would not be appropriate. Moreover, transition services are only effective if enrollees can access the community-based mental health services they need to avoid returning to the IMD setting. CMS should work with the Oregon to clarify its proposal and ensure it advances the state’s obligations to deliver community-based care under the Supreme Court’s *Olmstead* decision.20

**Removal of the EPSDT waiver is a vital improvement, but the demonstration continues to raise serious concerns and questions about access to EPSDT 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 adults under age 21 receive the full scope of services necessary for their healthy growth and development.

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The “T” of EPSDT entitles children access to all medically necessary services that Medicaid can cover, even if they are not covered for adults under the state plan. 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 subject to this waiver.

In its application, the state proposes to phase-out its waiver of EPSDT ending no later than January 1, 2024. The state suggests that during this lengthy wind down period 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. While we applaud the state’s decision to drop its waiver of EPSDT, we have significant concerns about the state’s proposal to continue using the prioritized list and questions about the implementation plans. It should also be noted that it is difficult to comment on the state’s proposal given the lack of detail.

We believe there is no clear purpose to continue using the list for children, but there is clear harm. The continued use of a list is incompatible with the basic purpose and design of EPSDT. While the state proposes to “adjust the Prioritized List to ensure that all medically necessary EPSDT services for the population of children and adolescents are covered,” this simply is not possible. EPSDT medical necessity is an individualized determination made between a provider and patient and cannot be defined at the population level. The HERC may place common pediatric services on the list, however there is no way to fully capture what providers will deem necessary for all individual children.

In practical terms, the continued use of a changeable list for children (even with an exceptions process) runs the risk of creating a de facto waiver of EPSDT. First, given the historical use of the list as exclusionary for children and the continued use of the list as a hard limit for adults, using the list in this “new way” for children will cause undue confusion for both providers and enrollees. Any notion of “over” and “under” the line will revert to “covered” and “not covered.” Secondly, given that the list and “coverage line” is subject to regular revision, it will create uncertainty for patients and providers about which services will be covered or require review in the future as the line moves. While we do not encourage the use of utilization management for EPSDT services, the state already has more appropriate flexibilities to implement utilization management mechanisms to promote use of high-value services for children.

We also have significant concerns about the implementation of this policy, based on the details we can garner from the application. First, the state proposes a “transition period” to phase out its waiver by January 1, 2024, yet there is no justification for this long delay. It is also 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

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21 Title XIX of the Social Security Act, §1905(t).
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.

Second, the application includes no explanation of the individualized medical necessity review process (including during 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 sufficient information about outreach or education to ensure that providers and families are informed of their 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.23 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.24

Our recommendation is that CMS deny the continued use of any extra list for children, regardless of the exceptions process. If, contrary to our suggestion, CMS allows the continued use of a list, it is even more critical that CMS require the state to publicly explain and implement a strong outreach and exceptions process plan.

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 of no benefit 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 individuals with incomes at or below 100 percent of the federal poverty level (FPL).25 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 was likely a budgetary necessity.

However, twelve years after the enactment of the Affordable Care Act expanding coverage to the “new adult group” there is no reason to continue limiting access to services for any population, nor does it appear permissible. Whereas previously the limited benefits set was increasing access to new coverage, that same limited benefits set is now reducing all eligibility groups’ coverage relative to the state plan standard to which they are entitled. Consequently, such a waiver is no longer consistent with the objectives of Medicaid. Further, rationing care is no longer a financial necessity. The waiver has simply become a tool for fiscal control for the state legislature and administration.

24 Chiquita Brooks-Lasure and Daniel Tsai, Op cit.
The state’s application does not include any measurement of the prioritized list’s impact on beneficiaries in its 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.

The closed formulary for accelerated approval drugs is unnecessary and will inhibit beneficiary access.

The proposed limitation on accelerated approval drugs would likely restrict beneficiary access to needed prescription drugs, especially new specialty drugs. The waiver application does not define the universe of accelerated approval drugs that may be subject to review and exclusion. As a result, the closed formulary could include all accelerated approval drugs, not just those drugs for which the manufacturer has not completed confirmatory clinical trials within FDA timeframes. In addition, the waiver application does not indicate the criteria used during the state’s review of accelerated approval drugs in determining whether drugs have limited or inadequate evidence of clinical efficacy and determining whether they will be excluded. However, in its original concept paper appended to the application, the state suggests it could make a determination of clinical inefficacy if any of the following is true: “Primary endpoints in clinical trials have not been achieved; Only surrogate endpoints have been reported; Clinical benefits have not been assessed; The drug provides no incremental clinical benefit within its therapeutic class, compared to existing alternatives.” Consequently, the application leaves the door open to excluding any drugs that have only met surrogate endpoints (which is, by definition, all accelerated approval drugs that have not converted to full FDA approval), irrespective of whether any initial results from confirmatory trials show failure to achieve endpoints or whether the confirmatory trials have not been completed according to FDA timeframes. As a result, beneficiaries are at risk of losing access to some accelerated approval drugs that they need.

The application does not outline any exception or appeals process for individuals denied access to prescription drugs nor does it include any groups exempt from these limitations. While concerning for all beneficiaries, this is particularly concerning for children if they are also subject to the EPSDT “list.” It should also be noted that the Medicaid Drug Rebate Program (MDRP) already ensures that Medicaid has the lowest drug prices, net of rebates and discounts, of federal programs and agencies, while ensuring beneficiary access through its open formulary protection. 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 requirement that only section 1902 is waivable and maintained that participating in the MDRP requires following all provisions of section 1927.

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) or Judith Solomon (Solomon@cbpp.org).

American College of Obstetricians and Gynecologists
Center on Budget and Policy Priorities
First Focus on Children
Georgetown University Center for Children and Families
National Association of Pediatric Nurse Practitioners
Primary Care Development Corporation