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April 13, 2022

The Honorable Xavier Becerra, Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave., S.W.
Washington, D.C. 20201

Re: Oregon's application for renewal of the Oregon Health Plan (OHP) 1115(a) Demonstration Waiver for the 2022-2027 demonstration period.

Dear Secretary Becerra:

The National Health Law Program (NHeLP) is a public interest law firm working to advance access to quality health care and protect the legal rights of low-income and underserved people. We appreciate the opportunity to comment on Oregon's application for renewal of the Oregon Health Plan (OHP) 1115(a) Demonstration Waiver for the 2022-2027 demonstration period.¹

We support some parts of Oregon's demonstration. In particular, we enthusiastically support the State's decision to abandon its waiver of EPSDT. At the same time, we have concerns about implementation of the EPSDT waiver withdrawal, and do not support the continued use of the prioritized list for children and adults. We also find the proposal to exclude coverage for certain outpatient prescription drugs deeply troubling. In addition, we have concerns about the legality, necessity, and practical impact of the request to provide services to people in custody in state facilities. Therefore, we strongly urge HHS to deny these components of Oregon's waiver application.

I. HHS Authority Under § 1115

For the Secretary to approve a project pursuant to § 1115, the project must meet four requirements.

First, the state must propose to conduct an “experimental, pilot, or demonstration” project. This demands a “novel approach” to program administration.² To evaluate whether a proposed project is a valid experiment, the Secretary needs to know what will be tested and how, at the point in time when the project is being approved.

Second, the project must promote the Medicaid Act’s objectives. According to Congress, the purpose of Medicaid is to enable states “to furnish[] medical assistance” to individuals “whose income and resources are insufficient to meet the costs of necessary medical services” and to provide “rehabilitation and other services to help such families and individuals attain or retain capability for independence or self-care.”³ Thus, the “central objective” of the Medicaid Act is “to provide medical assistance,” that is to provide health coverage.⁴

Third, the Secretary can only waive provisions set forth in § 1396a of the Medicaid Act. The Secretary cannot waive requirements contained in §§ 1396b through 1396w-5.⁵ Once the Secretary has acted under § 1115(a)(1) to waive compliance with designated provisions in § 1396a, § 1115(a)(2) provides that the costs of “such project” are “regarded as expenditures under the State plan” and, thus, paid for under the same statutory formula that applies for a state’s expenditures under its State plan.⁶ Section 1115(a)(2) does not create an independent “expenditure authority” for the Secretary to allow a state to ignore provisions of the Medicaid

¹ Oregon Health Authority, *Oregon’s application for renewal of the Oregon Health Plan (OHP) 1115(a) Demonstration Waiver for the 2022-2027 demonstration period* (Feb. 18, 2022) [hereinafter “Application”], <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/or/or-health-pln-extnsion-appl-2022-2027.pdf>.

² *Beno v. Shalala*, 30 F.3d 1057, 1069 (9th Cir. 1994).

³ 42 U.S.C. § 1396-1; 1396d(a) (defining “medical assistance” as provision of, or payment for, specified health care and services).

⁴ *Stewart v. Azar*, 366 F. Supp. 3d 125, 138 (D.D.C. 2019); *id.* at 144 (rejecting “promoting health” as an independent objective because the Medicaid Act is “designed ... to address not health generally but the provision of care to needy populations” through a health insurance program).

⁵ See 42 U.S.C. § 1315(a)(1).

⁶ *Id.* § 1315(a)(2).



Act outside of § 1396a or to rewrite the provisions in § 1396a or any other provision outside of § 1396a. To the contrary, it is a “clean-up” provision that merely provides the authorization necessary for federal reimbursement of expenditures for a project that has been approved under § 1115(a)(1).

Fourth, § 1115 allows approvals only “to the extent and for the period . . . necessary” to carry out the experiment.⁷ The Secretary cannot use § 1115 to permit states to make long-term policy changes.

II. Early Periodic Screening, Diagnosis and Treatment

We enthusiastically support Oregon’s decision to abandon its waiver of the EPSDT requirement. EPSDT provides a comprehensive array of preventive, diagnostic, and treatment services for all children under age 21. As CMS notes, “the EPSDT benefit is more robust than the Medicaid benefit for adults and is designed to assure that children receive early detection and care . . . The goal of EPSDT is to assure that individual children get the health care they need when they need it – the right care to the right child at the right time in the right setting.”⁸

HHS allowed Oregon to waive the EPSDT requirement in 1994, which enabled them to limit covered services to those included on a “prioritized list” determined by the governor-appointed Health Evidence Review Committee (HERC). This effectively eliminated the key EPSDT requirement that states cover all Medicaid services necessary to “correct or ameliorate” an individual child’s condition. Thus, ending this waiver is a welcome step that will restore access to the full scope of benefits, as intended by Congress.

Unfortunately, the State is proposing to retain its prioritized list. Though Oregon states that it plans to revise the list to cover all medically necessary pediatric services and, thereafter, allow an individualized medical necessity review, we do not believe this will protect children’s right to services under EPSDT. The State’s proposal is short on details as to how it will actually ensure

⁷ *Id.* § 1315(a); *see also id.* §§ 1315(e)(2), (f)(6) (limiting the extension of “state-wide, comprehensive demonstration projects” to one initial extension of up to 3 years (5 years, for a waiver involving Medicare-Medicaid eligible individuals) and one subsequent extension not to exceed to 3 years (5 years, for Medicare-Medicaid waivers).

⁸ Ctrs. for Medicare & Medicaid Servs., *EPSDT- A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents*, iii (June 2014).



that all services are covered. In addition, even the minimal details provided indicate that harm will result to children.

The concept of a closed list of services is incompatible with the purpose and design of EPSDT. Even though the State may intend to amend the prioritized list to ensure all medically necessary services are covered, it is not clear how that can be accomplished. EPSDT requires an individualized determination by a treating provider. There is no way to ensure that all services that may be necessary for a child will be included on a list.

We also have significant concerns about the implementation of this policy, based on what 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. It is not clear whether children will still be subject to the current prioritized list and how the agency will ensure that the children have access to an appeals process when they cannot access the services they need. More importantly, the application does not explain how the proper provision of services and access to notice and hearing rights will be monitored across CCOs. Also, the State must ensure that there is a strong public outreach process which meets the standard of § 1396a(a)(43) of the Social Security Act, which the application does not address. If HHS 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”). 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 about EPSDT services will impact children of color. As recognized by the Biden-Harris Administration, administrative burden has a disproportionate impact on families of color.⁹ Imposing additional burdens on families will undermine the stated goal of reducing disparities.

⁹ 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.



Finally, there is no legitimate experiment here. Oregon has been using this prioritized list for decades. The State has therefore had ample time to demonstrate how rationing health care services through application of this list has furthered the goals of the Medicaid program. However, it has not provided analysis or data to demonstrate that this “experiment” actually promotes the objectives of the Medicaid Act.

Our recommendation is that HHS deny the continued use of any extra list for children, and that it require that Oregon explain how it will ensure that children receive all medically necessary services during the transition period, including its plan to monitor the CCOs.

III. Use of a Prioritized List for Adults

Oregon originally received permission to create the prioritized list when it expanded coverage to adults with incomes at or below poverty in 1989.¹⁰ At that time, the population was not included in Title XIX of the Social Security Act and federal matching funds were not available. However, twelve years after the enactment of the Affordable Care Act expanding coverage to the adults not previously coverable except through a waiver, any justification for this waiver is gone. Whereas previously the theory was that a limited benefits package saved money, thus providing the means to cover additional people, 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, there is no support for the argument that rationing care is a financial necessity. The waiver has simply become a tool for fiscal control for the state legislature and administration.

Also problematic is the fact that the State’s proposed evaluation includes no measurement of the prioritized list’s impact on beneficiaries. It does not address important questions, such as which required services adults will lose access to, and what harms will that cause. It does not address the potential impact the exclusionary has on vulnerable populations such as pregnant women, or whether it will 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 any possible experimental purpose, we strongly believe that the State should be required to provide all mandatory Medicaid services for all populations.

¹⁰ Oregon Health Authority, “Prioritized List Overview,” <https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Prioritized-List-Overview.aspx>.



IV. Harmful Changes to Prescription Drug Coverage

Oregon has proposed drastic and harmful changes to Medicaid outpatient prescription drug coverage. It seeks to exclude coverage of medications approved under the FDA's "fast track" approval process – a more limited version of its original proposal for a closed formulary.

HHS should reject the request. Congress has established comprehensive, specific coverage requirements for Medicaid outpatient prescription drugs that work in conjunction with the requirement for generous manufacturers' rebates. HHS has no authority under § 1115 to waive these provisions, which rest outside of 42 U.S.C. § 1396a (in § 1396r-8). In addition, HHS should reject Oregon's proposal because there is nothing experimental in denying Medicaid enrollees access to drugs determined to be safe and effective by the FDA.

Oregon's proposal is not an experiment, but, rather, a mere cost-cutting proposal that will harm people with serious and life-threatening diseases and conditions, for whom there are no meaningful alternatives. Such a waiver would set a dangerous precedent and could lead to a race-to-the bottom whereby other states would seek to limit Medicaid prescription drug coverage to the detriment of low-income and vulnerable enrollees. Moreover, Oregon's proposed closed formulary is contrary to its purported goal to "rectify health inequities," as well as the Biden-Harris administration's commitment to "protect and strengthen Medicaid and the ACA and to make high-quality healthcare accessible and affordable for every American," and to "advance equity for all, including people of color and others who have been historically underserved."¹¹ HHS should reject this unlawful and harmful proposal.

A. Outpatient prescription drug protections may not be waived through § 1115

HHS has no authority to waive Medicaid outpatient prescription drug coverage requirements. As noted above, § 1115 may only be used to waive requirements of 42 U.S.C. § 1396a, and the outpatient prescription drug requirements are in 42 U.S.C. § 1396r-8.

¹¹ Letter from Gov. Kate Brown to Ctrs. for Medicare & Medicaid Svcs. Admin. Chiquita Brooks-LaSure (Feb. 2, 2022); Exec. Order No.14,009, *Strengthening Medicaid and the Affordable Care Act*, 86 Fed. Reg. 7793-7795 (Feb. 2, 2021), <https://www.govinfo.gov/content/pkg/FR-2021-02-02/pdf/2021-02252.pdf>; Exec. Order No. 13,985, *Advancing Racial Equity and Support for Underserved Communities Through the Federal Government*, 86 Fed. Reg. 7009-7013 (Jan. 25, 2021), <https://www.govinfo.gov/content/pkg/FR-2021-01-25/pdf/2021-01753.pdf>.



With this provision, Congress established broad coverage requirements to ensure access to outpatient prescription drugs for low-income Medicaid enrollees.¹² States that elect to provide outpatient prescription drug coverage must cover all FDA-approved drugs that are offered by any manufacturer that agrees to provide rebates.¹³ In exchange, the manufacturers enter into rebate agreements, which allow Medicaid programs to purchase prescription drugs at a significantly lowered cost.¹⁴ Oregon’s proposal to waive the broad coverage requirements, while retaining manufacturers’ rebates, would upend the fundamental structure of these interdependent statutory provisions. HHS has recognized as much.¹⁵

HHS recognized that rebates provided under the Medicaid Drug Rebate Program (MDRP) work in conjunction with the broad coverage requirements under § 1396r-8 when it rejected the “closed formulary” proposal from Massachusetts.¹⁶ HHS suggested that states would have to forgo rebates under the MDRP to exclude drugs and negotiate prices directly with manufacturers.¹⁷

We also note that Oregon has not made use of its authority under § 1396r-8 to establish a formulary and exclude drugs from Medicaid coverage. That provision allows a state to establish a formulary so long as certain conditions are met. The formulary must be developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed

¹² H.R. Rep. 101-881, 101st Cong. 2nd Sess. 1990, 1990 U.S.C.C.A.N. 2017.

¹³ 42 U.S.C. § 1396r-8(k)(2)(i).

¹⁴ 42 U.S.C. § 1396r-8(a)(1). The rebate structure has succeeded in lowering costs for states. MACPAC conducted an in-depth analysis comparing the cost of prescription drugs in Medicaid, commercial plans with closed formularies, and Medicare. Medicaid offers much broader coverage and pays far less, or at least the same, for most drugs when compared to commercial plans and Medicare. See Medicaid and CHIP Payment and Access Comm’n, *Findings from Phase 2 of Analysis on Medicaid Drug Formularies: Effects on Utilization and Spending* (Sept. 2019), <https://www.macpac.gov/publication/findings-from-phase-2-of-analysis-on-medicaid-drug-formularies-effects-on-utilization-and-spending/>.

¹⁵ See CMS, *Approval Letter for Massachusetts MassHealth Section 1115 Demonstration Amendment* (Jun. 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>.

¹⁶ See CMS, *Approval Letter for Massachusetts MassHealth Section 1115 Demonstration Amendment* (Jun. 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>.

¹⁷ *Id.*



by the Governor or the state's drug use review board.¹⁸ A state may only exclude an outpatient prescription drug from the formulary after finding the drug does not have a significant, clinical therapeutic advantage over other drugs, and the state must explain the basis for the exclusion in writing.¹⁹ The state must permit coverage of an excluded drug pursuant to a prior authorization program and on a case-by-case basis.²⁰

If HHS were to allow states to exclude drugs they are required to cover under federal law, it would disrupt the framework that Congress put in place ensuring drug access for Medicaid enrollees while providing states with generous rebates.

B. There is nothing experimental about Oregon's proposed closed formulary

Oregon has not proposed a valid experiment. The application suggests that Oregon is requesting the waiver to decrease its spending on drugs.²¹ However, Oregon does not say how much it spends on accelerated approval drugs in its Medicaid program; nor does it provide cost estimates for its proposal to exclude such drugs. There is good reason to think that Oregon's expectation of cost savings is overblown. Nationwide, Medicaid spending on accelerated approval drugs remained steady at 0.6% to 0.8% a year in the past decade.²² Oregon does not say whether it will exclude all, or just some accelerated approval drugs. Either way, the savings on prescription drug spending would be a fraction of a percent.

Additionally, in its "budget neutrality" predictions, Oregon does not factor in the cost of other medical services Medicaid enrollees will need if denied access to effective drug therapies. According to HealthCare.gov, the average cost of a three-day hospital stay is \$30,000; while

¹⁸ 42 U.S.C. § 1396r-8(d)(4)(A). See also David Bergman et al., National Academy for State Health Policy (NASHP), *State Experience in Creating Effective P&T Committees* (March 2006), https://nashp.org/wp-content/uploads/sites/default/files/medicaid_pandt.pdf.

¹⁹ 42 U.S.C. § 1396r-8(d)(4)(C).

²⁰ 42 U.S.C. § 1396r-8(d)(4)(C); see also *Pharmaceutical Research and Mfrs. of America v. Meadows*, 304 F.3d 1197, 1207-08 (11th Cir. 2006).

²¹ See Application at 72.

²² Kenneth E. Thorpe, PhD & Douglas Holtz-Eakin, PhD, *Limiting Medicaid Access to Accelerated Approval Drugs: Costs and Consequences*, AM J MANAG CARE (June 2021), <https://www.ajmc.com/view/limiting-medicaid-access-to-accelerated-approval-drugs-costs-and-consequences>.



some cancer treatments can cost hundreds of thousands of dollars.²³ Oregon must account for these additional costs when predicting the fiscal impact of its proposal to exclude medically necessary prescription drugs. In fact, there is a wealth of evidence showing that formulary restrictions have either a negative effect or no effect at all on pharmacy and medical costs.²⁴

Oregon also posits that its closed formulary would “incentivize drug sponsors to complete their regulatory obligations to demonstrate clinical benefit as laid out by the FDA upon approval.”²⁵ This is not plausible. According to the Congressional Budget Office (CBO), revenue generated by members of the Pharmaceutical Research and Manufacturers Association (PhRMA) exceeded \$450 billion in 2019 alone.²⁶ Oregon’s entire Medicaid program operates at just a fraction of that amount.²⁷ It is hard to imagine how the State’s exclusion of accelerated approval drugs would influence PhRMA processes.

In sum, the proposal is nothing more than a simple benefits cut, which Oregon hopes will save money – that does not satisfy the experimental requirement in § 1115.²⁸

²³ Dept. of Health and Human Svcs., HealthCare.gov, Protection from high medical costs, <https://www.healthcare.gov/why-coverage-is-important/protection-from-high-medical-costs/> (accessed April 2, 2022).

²⁴ Yujin Park et al., *The Effect of Formulary Restrictions on Patient and Payer Outcomes: A Systematic Literature Review*, 23 J. MANAGED CARE & SPECIALTY PHARM. 893, 898 (2017) (reviewing 59 unique studies and observing that the majority of “studies that included total or medical costs (in addition to pharmacy costs)... showed either negative effect on total, medical, or pharmacy costs or no effect on pharmacy costs”); Laura E. Happe et al., *A Systematic Literature Review Assessing the Directional Impact of Managed Care Formulary Restrictions on Medication Adherence, Clinical Outcomes, Economic Outcomes, and Health Care Resource Utilization*, 20 J. MANAGED CARE & SPECIALTY PHARM. 677, 681 (2014) (reviewing 93 studies and concluding “there was no distinct trend in the direction of association of economic outcomes with formulary restrictions”).

²⁵ Application at 71.

²⁶ CBO, Research and Development in the Pharmaceutical Industry (April 2021), Figure 5 at 13, <https://www.cbo.gov/system/files/2021-04/57025-Rx-RnD.pdf>.

²⁷ Oregon spent \$2.6 billion on all Medicaid services in FY 2020. See KFF, *Federal and State Share of Medicaid Spending*, <https://www.kff.org/medicaid/state-indicator/federalstate-share-of-spending/?dataView=1¤tTimeframe=0&sortModel=%7B%22colld%22:%22Location%22,%22sort%22:%22asc%22%7D>.

²⁸ See *Beno v. Shalala*, 30 F.3d 1057, 1069 (9th Cir. 1994).



C. Oregon’s closed formulary proposal does not promote the objectives of the Medicaid Act

FDA accelerated approval drugs are safe and effective

In an effort to justify its proposal, Oregon repeatedly contends that drugs approved under the FDA’s accelerated approval process “have not yet demonstrated clinical benefit.”²⁹ This is untrue. The FDA first established accelerated approval through regulation in 1992, largely in response to the AIDS pandemic and repeated protests against drug approval red tape.³⁰ Congress codified the accelerated approval pathway in 1997, and updated and expanded the accelerated approval pathway in 2012.³¹

Accelerated approval is based on the FDA’s finding that a drug is safe and effective for its intended use — the same approval standard used for traditional approval.³² Accelerated approval simply permits FDA to accept a different type of data from traditional drug approval — relying on a “surrogate endpoint that is reasonably likely to predict clinical benefit” and that can be measured earlier than irreversible morbidity or mortality.³³ When finalizing regulations for accelerated approval, the FDA emphasized: “[t]he evidence available at the time of approval under this rule will meet the statutory standard, in that there must be evidence from adequate and well-controlled studies showing that the drug will have the effect it is represented to have

²⁹ Application at 71.

³⁰ Dept. of Health and Human Svcs., FDA, Final Rule: New Drug, Antibiotic, and Biological Drug Product Regulations; Accelerated Approval, 57 Fed. Reg. 53942, 52944 (Dec. 11, 1992), <https://tile.loc.gov/storage-services/service/ll/fedreg/fr057/fr057239/fr057239.pdf>. See also Grossman, Lewis A., AIDS Activists, FDA Regulation, and the Amendment of America’s Drug Constitution, AM J LAW & MED (Feb. 27, 2016), https://digitalcommons.wcl.american.edu/facsch_lawrev/761/; Jim Eigo, et al., ACT UP/NY, *FDA Action Handbook* (Sept. 12, 1988), <https://actupny.org/documents/FDAhandbook1.html>.

³¹ Food and Drug Administration Regulatory Modernization Act of 1997, Pub L No. 105-115, 111 Stat 2296 (1997); Food and Drug Administration Safety and Innovation Act of 2012, Pub L No. 112-144, 126 Stat 993-1132 (2012). See also National Organization for Rare Diseases, *FDA’S Accelerated Approval Pathway: A Rare Disease Perspective* (June 2021), https://rarediseases.org/wp-content/uploads/2021/06/NRD-2182-Policy-Report_Accelerated-Approval_FNL.pdf.

³² 21 U.S.C. § 356(c), cross referencing 21 U.S.C. § 355(c).

³³ 21 U.S.C. § 356(c).



in its labeling.”³⁴ Furthermore, the FDA has authority to amend a drug’s labeling or withdraw approval if follow up studies do not support accelerated approval data.³⁵

The Medicaid and CHIP Payment and Access Commission (MACPAC) examined accelerated approval drugs, responding to concerns raised by states regarding the high cost of some “specialty” drugs. In its report to Congress, MACPAC emphasized the need for “maintaining access for beneficiaries” and recommended “no changes to the obligation to cover these drugs.”³⁶

HHS also recognized there is no distinction between drugs approved under the FDA accelerated approval and traditional approval processes. In a Medicaid Rebate Program Notice, HHS instructed states to treat accelerated approval drugs as any other covered outpatient prescription drug, emphasizing that accelerated approval “does not alter the standards of evidence [...] including the standards regarding whether a product is safe and effective.”³⁷

³⁴ Dept. of Health and Human Srvs., FDA, *Final Rule: New Drug, Antibiotic, and Biological Drug Product Regulations; Accelerated Approval*, 57 Fed. Reg. 53942, 52944 (Dec. 11, 1992), <https://tile.loc.gov/storage-services/service/ll/fedreg/fr057/fr057239/fr057239.pdf>.

³⁵ See FDA, *Withdrawn | Cancer Accelerated Approvals*, <https://www.fda.gov/drugs/resources-information-approved-drugs/withdrawn-cancer-accelerated-approvals> (last visited April 2, 2022).

Oregon cites to concerns that some pharmaceutical manufacturers may not be conducting the post-approval follow up research to justify its waiver. However, this concern should be address through the regulatory or legislative process, not through a Medicaid waiver. See, e.g., House Energy and Commerce Committee, Subcommittee on Health, *Public Hearing: The Future of Medicine: Legislation to Encourage Innovation and Improve Oversight*, March 17, 2022), <https://energycommerce.house.gov/committee-activity/hearings/hearing-on-the-future-of-medicine-legislation-to-encourage-innovation>.

³⁶ MACPAC, *Report to Congress on Medicaid and CHIP 2021, Ch. 1 Addressing High Cost Specialty Drugs* (June 2021) at 2, <https://www.macpac.gov/wp-content/uploads/2021/06/Chapter-1-Addressing-High-Cost-Specialty-Drugs.pdf>. To help address states’ concerns, MACPAC recommended Congress approve an increased federal medical assistance percentage (FMAP) for certain high cost, specialty drugs. *Id.*

³⁷ Ctrs. for Medicaid and CHIP Srvs., *Medicaid Drug Rebate Program Notice No. 185, State Medicaid Coverage of Drugs Approved by the FDA under Accelerated Approval Pathway* (June 27, 2018), <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-185.pdf>.



Oregon’s § 1115 application seeks “to use its own rigorous review process” for drugs the FDA has already found to be safe and effective.³⁸ In essence, Oregon wants to substitute its judgment for drug safety and efficacy for that of the FDA. Oregon does not explain how it will review drugs, what standards it will employ, or who within the state will conduct such reviews. Moreover, Oregon does not explain why its drug evaluation should supersede that of the FDA, a \$6.2 billion federal agency specifically charged by Congress to evaluate prescription drug safety and efficacy, and which is recognized world-wide as the “gold standard” for drug review.³⁹

Oregon’s proposal could lead to more than fifty different state standards, which would undermine federal drug approval authority and lead to dangerous, potentially deadly implications.

Excluding accelerated approval drugs would harm highly vulnerable populations

Oregon’s proposal, to deny people with significant or life-threatening health conditions access to FDA-approved drugs, will have an entirely predictable result. People will die.

By definition, accelerated approval drugs are for people with serious or life-threatening conditions, and for whom the drug addresses “unmet medical needs for such disease or condition.”⁴⁰ Oregon’s application does not explain if its default will be to exclude all accelerated approval drugs, and then it will decide which drugs to cover on a case-by-basis; or if will cover these drugs and then decide which to exclude. Nowhere in the application does Oregon describe how it will review drugs or who might be affected if its proposal is approved.

However, drugs subject to Oregon’s Medicaid coverage exclusion are used to treat serious, life-threatening, and debilitating illnesses. Many accelerated approval drugs are oncological.⁴¹

³⁸ Application at 71.

³⁹ FDA, The President’s FY2022 Budget Request for FDA (June 10, 2021), <https://www.fda.gov/news-events/congressional-testimony/presidents-fy2022-budget-request-fda-06102021#:~:text=Today%2C%20I%20am%20pleased%20to,the%20FY%202021%20Enacted%20level.>

⁴⁰ 21 U.S.C. § 356(b).

⁴¹ See FDA, *Ongoing | Cancer Accelerated Approvals*, <https://www.fda.gov/drugs/resources-information-approved-drugs/ongoing-cancer-accelerated-approvals> (last visited April 2, 2022).



They include drugs used to treat blood cancers, for which surgeries and other forms of medical intervention are not possible.⁴²

At a recent forum convened by the Reagan-Udall Foundation for the FDA, Katherine Couvillon described her experience after being diagnosed with stage four metastatic cancer and facing a life-expectancy of just three years.⁴³

“I just sat in my car [...] and cried and tried to summon up the words to tell my husband, that I was going to die [...] I thought at that time I'm not going to live to see my 40th birthday.”⁴⁴

Couvillon’s oncologist prescribed IBRANCE®, which in 2015 had just been approved under the FDA’s accelerated approval program.⁴⁵ Couvillon credits the new treatment with helping keep her alive to see her 40th birthday. Although her cancer has returned and Couvillon faces an uncertain future, she emphasized:

“All of us are just hoping that we can live long enough to see a cure or the next drug that's worthy of accelerated approval. And yet still one hundred and fourteen of us are dying every day from metastatic breast cancer and we just don't have time to wait. Accelerated approval, I believe, gave me five years that I wouldn't have had otherwise and a wonderful quality of life during those five years I'm so thankful and I'm just looking forward for the next drug that's going to give me more time.”⁴⁶

Accelerated approval can also help address longstanding disparities and racial inequities in health care. Sickle cell disease is a lifelong, inherited blood disorder affecting mostly African

⁴² See, e.g., Leukemia & Lymphoma Society, Press Release, FDA Approves New Drug for Patients with Rare Blood Cancer (Feb. 28, 2022), <https://www.lls.org/news/fda-approves-new-drug-patients-rare-blood-cancer-myelofibrosis>. See also Chambers JD, Thorat T, et al., *Drugs Cleared Through The FDA's Expedited Review Offer Greater Gains Than Drugs Approved By Conventional Process*, Health Affairs (Aug. 2017), <https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.1541>.

⁴³ Reagan-Udall Foundation for the FDA, *Accelerated Approval Program 30 Years On: Insights and Experiences* (March 11, 2022), <https://reaganudall.org/news-and-events/events/accelerated-approval-program-virtual-public-meeting>.

⁴⁴ Id. Meeting Transcript at 36, <https://reaganudall.org/sites/default/files/2022-03/Acc%20Appr%20Transcript%20031622.pdf>.

⁴⁵ FDA, Palbociclib (IBRANCE), <https://www.fda.gov/drugs/resources-information-approved-drugs/palbociclib-ibrance> (last visited April 8, 2022).

⁴⁶ Reagan-Udall Foundation, *supra* note 43, Meeting Transcript at 37-38.



Americans that causes red blood cells to become abnormally sickle or crescent shaped, leading to episodes of extreme pain and organ and tissue damage. As researchers noted in the *New England Journal of Medicine*, “Although [sickle cell disease] was first described more than 100 years ago, the development of disease-modifying therapies has stagnated because of inadequate research funding, attributable at least in part to structural racism.”⁴⁷

In 2019, the FDA granted accelerated approval for voxelotor to treat sickle cell disease in persons over age twelve, only the fourth drug available to treat the disease.⁴⁸ In 2021, the FDA extended use of the drug for pediatric patients aged four to eleven years.⁴⁹

Advocate Teonna Woolford, who is living with sickle cell disease, described her experience after failing with other forms of treatment:

“It was clear that I was running out of options, and this is something that was common in the sickle cell community because we've been left out of clinical research for so long, and then in 2019, within a two year time span, we had two FDA approved drugs through the process of accelerated approval, and that's been amazing like, not just for me, but for my community.”⁵⁰

Oregon’s proposal to exclude accelerated approval drugs from Medicaid would exacerbate health disparities and deprive people like Teonna Woolford and Katherine Couvillon the opportunity to live their full lives.

Oregon also says that “we will ensure continued pharmacy protections for members.”⁵¹ It is unclear what the State means here. If OHA were to ensure pharmacy protections, it would not

⁴⁷ Alexandra Power-Hays, M.D., and Patrick T. McGann, M.D., *When Actions Speak Louder Than Words — Racism and Sickle Cell Disease*, *N ENGL J MED* (Nov. 12, 2020), <https://www.nejm.org/doi/full/10.1056/NEJMp2022125>.

⁴⁸ FDA, *FDA approves novel treatment to target abnormality in sickle cell disease* (Nov. 19, 2019), <https://www.fda.gov/news-events/press-announcements/fda-approves-novel-treatment-target-abnormality-sickle-cell-disease>.

⁴⁹ FDA, *FDA approves drug to treat sickle cell disease in patients aged 4 up to 11 years* (Dec. 17, 2021), <https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-drug-treat-sickle-cell-disease-patients-aged-4-11-years#:~:text=FDA%20has%20granted%20accelerated%20approval,older%20with%20sickle%20cell%20disease>.

⁵⁰ Reagan-Udall Foundation, *supra* note 43, Meeting Transcript at 33.

⁵¹ Application at 72.



be seeking to exclude drugs used to treat severe or life-threatening illnesses from its Medicaid program.

D. HHS should not approve any § 1115 waiver that relies on QALYs to ration care

Oregon cites to a study by the Institute for Clinical and Economic Review (ICER) to support its proposal to exclude certain drugs from Medicaid coverage.⁵² The reference to ICER is troubling, because it foreshadows that Oregon will employ an ICER metric, quality adjusted life years (QALYs), when making its coverage determinations. QALYs are sometimes used to calculate cost-effectiveness of a drug or other medical intervention. The National Council on Disability (NCD), an independent federal agency making recommendations to the President and Congress to enhance the quality of life for all Americans with disabilities and their families, recently concluded, based on this evidence, the use of QALYs is discriminatory or potentially discriminatory.⁵³ HHS previously rejected Oregon’s request for demonstration authority to use QALYs to allocate resources in their Medicaid program in the early 1990s.⁵⁴ Congress also prohibited the use of QALYs in Medicare and the Patient Centered Outcomes Research Institute (PCORI) within the Affordable Care Act.⁵⁵

During the state comment period, Oregon Health Plan members, advocates, as well as health system representatives urged the Oregon Health Authority (OHA) to renounce the use of QALYs and other discriminatory measures.⁵⁶ However, the OHA declined to do so, and defended its continued uses of QALYs when “evaluating cost-effectiveness” of treatments.⁵⁷

We urge HHS to reject any use of QALYs in Medicaid coverage decisions, including Oregon’s § 1115 waiver program.

⁵² Application at 72, citing to Kaltenboek, Mehlman, & Pearson, ICER, *Strengthening the Accelerated Approval Pathway: An Analysis of Potential Policy Reforms and their Impact on Uncertainty, Access, Innovation, and Costs* (April 26, 2021).

⁵³ Nat’l. Council on Disability, *Quality-Adjusted Life Years and the Devaluation of Life with Disability: Part of the Bioethics and Disability Series* (Nov. 6, 2019), https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf.

⁵⁴ *Id.* at 45-46

⁵⁵ *Id.* at 46

⁵⁶ Application at 243-244.

⁵⁷ Application at 243.



V. Transitional services and services provided to meet social needs

Medicaid beneficiaries are entitled to notice and an opportunity for hearing when services are denied, terminated, or reduced. 42 C.F.R. §§ 431.201, 431.220(a)(1), 438.400(b), 438.402, 438.406. These flexible services are provided through the Medicaid program and paid for with Medicaid dollars, thus they are Medicaid services subject to the same due process protection as any others. However, Oregon’s proposal does not mention this requirement and gives no indication that it will require CCOs to give enrollees due process rights when it denies or terminates transitional services and services provided to meet social needs. HHS should ensure that the State recognizes this right, requires the CCOs to honor the right, and monitors whether due process rights are observed.

Moreover, it appears that Oregon will continue to only offer these services to those enrolled in a CCO. These services are not available to fee-for-service OHP members. If the State expands Medicaid services to include important but non-traditional “health related services,” these services must be available to all OHP enrollees.

Finally, we think it is important to note that Oregon is proposing to spend Medicaid money on social determinants of health, while denying coverage for actual health care treatment through use of the prioritized list. We firmly believe that Oregon would better achieve its stated goals by providing both adequate medically necessary and appropriate health care and also addressing social determinants of health.

VI. Waiver of the Exclusion for Services Provided to Individuals in Public Institutions

A. A waiver is not necessary to accomplish many of the goals of the proposal

Oregon has requested authority to cover Medicaid services for children and adults in state custody – both in carceral settings and IMDs. We wholeheartedly support Oregon’s goal of ensuring that individuals leaving custody have the health care services they need to successfully transition back to the community. We also agree that it is crucial to ensure that people in these settings are enrolled in a Medicaid managed care plan and connected with care upon release. But, as explained above, we do not support using “expenditure authority” to allow waiver of the exclusion of coverage of services provided in public institutions. Moreover, we have serious concerns about the policy implications of expanding Oregon’s ability to provide services in institutional settings rather than the community.



Some of the measures Oregon proposes to take, such as ensuring that individuals are enrolled in CCOs prior to release and providing services upon discharge, do not require any waivers. States can and do enroll individuals in Medicaid and in MCOs before discharge without requiring waivers.⁵⁸ Many of the barriers to re-enrollment and connection with services have no connection to the exclusion of coverage in public institutions. In particular, Oregon states that it takes 10-14 days after an individual is released from an IMD or carceral setting to be re-enrolled in a CCO. However, Oregon never explains why this is and why this time frame cannot be shorter. Because there is no barrier to completing re-enrollment paperwork prior to release or connecting a person with care, it is not clear why someone needing services should go "without those critical services for weeks" upon release. HHS should require an explanation as to why a waiver is needed to address a problem apparently unrelated to any federal Medicaid requirements.

In addition, we have questions about the proposal to provide "limited OHP benefits and CCO enrollment and transition services upon release" for those leaving facilities. The State does not describe the nature of the services to be covered, the delivery mode, or how they differ from care coordination already provided. Without more, HHS will have no way to determine whether this measure can achieve its stated goals and avoid negative outcomes and wasted money.

B. Covering services indefinitely in jail and juvenile detention is harmful

We are particularly concerned about the proposal to cover full OHP benefits for all adults in jail and youth in juvenile detention. This creates a substantial risk that services already covered by jail providers will simply be reimbursed with federal funds instead of state dollars, shifting the costs without improving care, coordination, or health outcomes.

Juvenile detention centers are particularly ill-suited to providing treatment. Carceral settings are not therapeutic environments. In fact, "incarceration is antithetical to mental health"⁵⁹ and is

⁵⁸ See, e.g., Cal Health Pol'y Strategies, Policy Brief: Toward a Comprehensive Model of Integration for Justice-Involved Individuals Using Medi-Cal Managed Care Organizations (MCOs) (Feb. 2019); Jocelyn Guyer et al., State Strategies for Establishing Connections to Health Care for Justice-Involved Populations: The Central Role of Medicaid (Jan. 11, 2019).

⁵⁹ Sarah Kahn, *Olmstead as a Tool for Decarceration*, 11 U.C. IRVINE L. REV. 2021, at 1441.



likely to create or exacerbate mental health conditions.⁶⁰ It is difficult to provide quality mental health treatment in corrections facilities because “prisoners are reluctant to open up in environments where they do not feel physically or psychologically safe.”⁶¹ Overcrowded facilities also decrease psychological well-being and increase risk of suicide.⁶² Incarcerating children and young adults can cause serious harm to youth who are separated from their family and community, sometimes by hundreds of miles and with few ways to stay connected.⁶³ Incarceration during adolescence and early adulthood has also been shown to have long-term adverse impacts on individuals’ health.⁶⁴ The separation, often compounded by traumatic experiences endured within the facilities, can cause lasting physical and mental health issues for these children. Black and Indigenous youth are consistently incarcerated and sentenced at higher rates than white youth — a disparity that persists as overall youth confinement is declining.⁶⁵ Often these young people come from low-income and disinvested communities where a lack of resources diminishes the opportunities to fully recover from being in confinement.

Many youth facilities have policies and practices similar to the adult system, where youth are not allowed outside of their rooms without handcuffs or in public places without foot shackles⁶⁶ and sometimes placed in solitary confinement for days at a time or subjected to physical and

⁶⁰ Lorna Collier, *Incarceration Nation*, 45 MONITOR ON PSYCHOLOGY 56 (2014).

⁶¹ *Id.*

⁶² *Id.*

⁶³ Vincent Schiraldi, *Can We Eliminate the Youth Prison? (And What Should We Replace It With)?* Square One Project, June 2020, <https://squareonejustice.org/paper/can-we-eliminate-the-youth-prison-and-what-should-we-replace-it-with-by-vincent-schiraldi-june-2020/>.

⁶⁴ Christopher Wildeman and Emily Wang, *Mass Incarceration, Public Health, and Widening Inequality in the USA*, THE LANCET 389, April 2017, [https://doi.org/10.1016/S0140-6736\(17\)30259-3](https://doi.org/10.1016/S0140-6736(17)30259-3); Michael Massoglia and Brianna Remster, *Linkages Between Incarceration and Health*, PUBLIC HEALTH REPORTS, May 1, 2019, <https://doi.org/10.1177/0033354919826563>.

⁶⁵ No Kids in Prison, “Racial Disparity of Incarcerated Youth,” <https://www.nokidsinprison.org/explore/racial-disparity-of-incarcerated-youth/>; Douglas Blackmon, *Slavery by another name: The re-enslavement of Black people in America from the Civil War to World War II*, Doubleday, 2008; Balestra Media, “Jim Crow Juvenile Justice: Closing Youth Prisons is a Racial Justice Issue,” April 2018, <http://www.balestramedia.com/blog/2018/4/5/jim-crow-juvenile-justice-closing-youth-prisons-is-a-racial-justice-issue>.

⁶⁶ Candace Johnson & Mae C. Quinn, *Chaining Kids to the Ever Turning Wheel: Other Contemporary Costs of Juvenile Court Involvement*, WASH. & LEE L. REV. 2016, at 159, <https://scholarlycommons.law.wlu.edu/wlulr-online/vol73/iss1/4/>.



chemical restraints.⁶⁷ For example, youth facilities may administer powerful antipsychotic drugs often prescribed for bipolar disorder or schizophrenia to young people who have not been diagnosed with a mental illness.⁶⁸ In addition, youth often experience sexual abuse by other youth, correctional officers, and other staff, which can lead to a host of mental health issues that often go unaddressed, resulting in long-term harm.⁶⁹

Thus, allowing this waiver is not likely to advance the stated goals of the proposal to reduce health disparities and improve care. Rather, it creates a risk the children will experience more harm.

C. Providing Medicaid services in carceral settings may violate the ADA

Providing services for the duration of a juvenile's detention risks turning these settings into *de facto* institutions. Jails, prisons, and youth correction centers are perhaps the most segregated and least integrated settings in which public services can be provided. Thus, providing Medicaid services in this environment risks running afoul of the mandate of Title II of the Americans with Disabilities Act (ADA) prohibiting discrimination on the basis of disability and requiring that publicly funded services be provided in the most integrated setting appropriate to the needs of people with disabilities.⁷⁰ This requirement was interpreted by the Supreme Court in *Olmstead v. L.C.* to require states to provide Medicaid services in the community when appropriate to a person's needs, taking into account the needs of others with disabilities.⁷¹ Courts have found that the integration mandate applies to services provided in carceral settings and incarcerated people have successfully challenged isolation and delays in competency procedures.⁷² For example, a class of individuals with mental illness brought suit under the ADA and other laws to challenge New York's practice of holding them past their

⁶⁷ The Annie E. Casey Foundation, *Maltreatment in Juvenile Correctional Facilities* (June 2015), <https://www.aecf.org/resources/maltreatment-of-youth-in-us-juvenile-corrections-facilities/>.

⁶⁸ Ashley Norton, *The Captive Mind: Antipsychotics as Chemical Restraint in Juvenile Detention*, J. CONTEMP. HEALTH L. & POL'Y 2012, at 152 <https://scholarship.law.edu/cgi/viewcontent.cgi?article=1029&context=ichlp>.

⁶⁹ Patrick McCarthy, Vincent Schiraldi & Miriam Shark, *Future of Youth Justice: A Community-Based Alternative to the Youth Prison Model*, Nat'l Inst. Justice (Oct. 2016), <https://nij.ojp.gov/library/publications/future-youth-justice-community-based-alternative-youth-prison-model>.

⁷⁰ 42 U.S.C. § 12132, 35 C.F.R. § 135.130(d). Section 504 of the Rehabilitation Act has the same requirement, applicable to recipients of federal funding. 29 U.S.C. § 794; 28 C.F.R. § 41.51.

⁷¹ 527 U.S. 581, 600-01 (1999).

⁷² Kahn, *supra* note 32, at 1452 (citing Sahar Takshi, Note, *Behind Bars and in the Hole: Applying Olmstead to Incarcerated Individuals with Mental Illness*, 2 GEO. J. ON POVERTY L. & POL'Y 319, 342 (2020) (collecting cases)).



prison release dates and failure of the state to provide community-based mental health, housing, and supportive services upon release.⁷³

Thus, providing Medicaid coverage for services for the duration of a juvenile's detention means that the State is covering services in the most segregated setting possible. This potentially violates the ADA, which cannot be waived by the Secretary. Moreover, the proposal has the potential to divert funding from community placements for juveniles with mental health conditions, increasing the incentive to incarcerate them in the first instance because of a shortage of community based treatment options. This would violate § 1115 because it is inconsistent with furnishing medical assistance in the best interests of recipients. We note that the State has not sought a waiver of 42 U.S.C. § 1396a(a)(19) and, thus, must continue to adhere to that requirement.

It is important to note that thousands of children around the country are housed in juvenile detention centers because they are waiting for community based mental health services.⁷⁴ Children are regularly placed in juvenile justice settings because mental health services were unavailable in the community.⁷⁵ Services provided in juvenile detention cannot meet this need and covering them with Medicaid funds poses a risk of siphoning funds away from community based services.

Similarly, to the extent that waivers of the IMD exclusion allow states to obtain FFP for services that would otherwise be paid for by the state, such waivers undermine the strong incentive states have to quickly discharge individuals in community-based mental health services, thus undermining community integration and the Olmstead mandate.

⁷³ *M.G. v. N. Y. State Office of Mental Health*, No. 19-CV-639, 2021 WL 5299244 (S.D. N.Y. Nov. 15, 2011) (denying motion to dismiss).

⁷⁴ See, e.g., Staff of H. Comm. Gov't Reform, 108th Cong., Rep. on Incarceration of Youth Who Are Waiting for Community Mental Health Services in the U.S. (2004); Joseph J. Coccozza, *Addressing the Mental Health Needs of Youth in Contact with the Juvenile Justice System in System of Care Communities: An Overview and Summary of Key Issues*, Sept. 2010 (noting "many youth with mental health needs end up in the juvenile justice system not because of the seriousness of their offenses but because of their need for mental health treatment that is otherwise unavailable in the community.")

⁷⁵ Coccozza, *supra* note 47, at 1.



VII. Conclusion

While NHeLP supports the use of § 1115 to implement experimental projects that are likely to promote the objectives of the Medicaid Act, we strongly object to any efforts to use this law to skirt essential provisions that Congress has placed in the Medicaid Act to protect Medicaid beneficiaries and ensure that the program operates in their best interests.

We have included numerous citations to supporting research, including direct links to the research. We direct HHS to each of the materials we have cited and made available through active links, and we request that the full text of each of the studies and articles cited, along with the full text of our comment, be considered part of the formal administrative record for purposes of the Administrative Procedure Act. If HHS is not planning to consider these materials part of the record as we have requested here, we ask that you notify us and provide us an opportunity to submit copies of the studies and articles into the record.

If you have further questions, please contact Sarah Somers (somers@healthlaw.org) or Wayne Turner (turner@healthlaw.org).

Sincerely,



Jane Perkins
Legal Director

