

December 20, 2021

Director Patrick Allen
Oregon Health Authority
Health Policy and Analytics Medicaid Waiver Renewal Team
Attn: Michelle Hatfield
500 Summer St. NE, 5th Floor, E65
Salem, OR 97301

Re: Comments on Oregon’s Application for Renewal and Amendment of Oregon Health Plan, Section 1115 Demonstration Waiver

Dear Director Allen:

The Pharmaceutical Research and Manufacturers of America (“PhRMA”) writes to share its concerns with the proposal to amend the Oregon Health Plan (“OHP”) to adopt a commercial-style closed formulary approach that would potentially exclude a vast number of Food and Drug Administration (“FDA”)-approved drugs (“Proposed Amendment”).¹ The Proposed Amendment is included in the Application for Renewal and Amendment, Oregon Health Plan 1115 Demonstration Waiver (“Application”)² that was posted for public comment by the Oregon Health Authority (“OHA”) on December 7, 2021.

PhRMA represents the country’s leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA has a long-standing interest in promoting Medicaid members’ access to quality care and is concerned that Oregon’s proposal to waive sections of the Medicaid drug rebate statute to implement the Proposed Amendment will reduce and ration access to lifesaving medicines.

We understand that the state of Oregon faces considerable challenges in ensuring residents have access to quality, affordable health care, and PhRMA remains committed to ensuring that needed medicines are accessible for Medicaid members. Consistent with our priority of building a more just, equitable health care system, PhRMA believes that diversity, equity, and inclusion are essential to the discovery of new medicines and that people of all ethnic and racial backgrounds should have equitable access to treatment. As such, we are heartened to see the state’s commitment to improving equitable access to health care within Medicaid by addressing health equity and social determinants of health. However, Oregon’s proposal to waive

¹ OHA, Application for Renewal and Amendment, Oregon Health Plan 1115 Demonstration Waiver 30–32 (as revised Dec. 7, 2021). In the Application, OHA also proposes to, among other things, extend its existing OHP Medicaid Demonstration Waiver for an additional five years, effective as of July 1, 2022. PhRMA’s comment letter addresses only the Proposed Amendment that would waive “§1902(a)(54) insofar as it incorporates §1927(d)(1)(B)” in order to adopt a commercial-style closed formulary approach and exclude from the formulary drugs with limited or inadequate evidence of clinical efficacy. PhRMA takes no position with respect to the other components of OHA’s Application.

² Id. at 1.

“§1902(a)(54) insofar as it incorporates §1927(d)(1)(B)” to allow the state to impose a closed formulary and exclude drugs “with limited or inadequate evidence of clinical efficacy” does not promote those objectives; relies on flawed models to assess clinical/cost effectiveness that undervalues the lives of vulnerable populations; exacerbates health inequity; and fails to satisfy requirements for approval under Social Security Act (“SSA”) § 1115.³ The Proposed Amendment will impede access to medically necessary drugs for more than 700,000 Oregonians⁴ and raises serious concerns about the long-term impact on some of the sickest and poorest individuals in need of medical assistance. Moreover, the Proposed Amendment is ill-advised for both legal and policy reasons and should be withdrawn from the Application.

Our comments follow the outline below:

- I. The Proposed Amendment Does Not Meet the Requirements for Approval Under Social Security Act § 1115**
 - A. Waiving the Medicaid Rebate Statute’s Drug Coverage Requirements Would Not Promote Medicaid Objectives**
 - B. The Medicaid Rebate Statute Is a Package Deal that Cannot Be Torn Apart by a Selective Waiver of Its Coverage Requirements Alone**
 - C. A Closed Formulary Initiative is Not an “Experimental, Pilot, or Demonstration Project” Authorized Under Section 1115**
 - D. The Proposed Amendment Lacks Sufficient Details to Provide a Meaningful Opportunity for Public Comment**
- II. Cost Containment Tools to Control Pharmacy Expenditures are Currently Available Under Section 1927 and Other Provisions**
- III. Restricting Medicaid Drug Coverage Would Exacerbate Existing Health Inequities**
- IV. The Proposed Amendment Ignores Research Showing that Closed Formularies Hurt Patients, Lower Adherence, and Do Not Reduce Health Care Costs**

³ Social Security Act (SSA) § 1115.

⁴ May 2021 Medicaid and CHIP Enrollment Highlights, CMS (2021) <https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-enrollment-data/report-highlights/index.html>.

I. The Proposed Amendment Does Not Meet the Requirements for Approval Under Social Security Act § 1115

Oregon's Proposed Amendment fails to satisfy the requirements of the SSA in several important respects. First, the Proposed Amendment would not meet the requirement that a Section 1115 demonstration program be "likely to assist in promoting [Medicaid] objectives."⁵ Allowing a wholesale waiver of the drug coverage requirements in the rebate statute would not promote this objective, but would instead reduce members' access to needed medications and affect their health adversely. Second, waiving the Medicaid rebate statute's coverage requirements alone (without waiving the requirements for manufactures to pay rebates) would impermissibly tear apart the legislative bargain reflected in the statute.⁶ A state's coverage obligations are not severable from manufacturer rebates, and Oregon's proposal would violate the statutory covenant enshrined in the Medicaid rebate statute by doing so. Third, the Proposed Amendment fails to specify how it will serve as an "experimental" or "demonstration" project as required under Section 1115. The Proposed Amendment appears to impermissibly propose a series of cost cutting measures without research metrics to determine if the additional flexibilities the state is requesting further the core objectives of the Medicaid program. Finally, the Proposed Amendment lacks sufficient details to provide a meaningful opportunity for public comment.

A. Waiving the Rebate Statute's Drug Coverage Requirements Would Not Promote Medicaid Objectives

Any Section 1115 demonstration project must be "likely to assist in promoting the objectives of [Medicaid]."⁷ Oregon proposes to waive "§1902(a)(54) insofar as it incorporates §1927(d)(1)(B)" in order to establish a closed formulary. The closed formulary would not comply with the rebate statute's more patient-protective prescription drug coverage standards. The Proposed Amendment contains limited information on how drugs would be excluded from the formulary, but it appears that a drug could be excluded for two different reasons: (1) to reduce the number of drugs in a class to one so that "manufacturers could be offered an essentially guaranteed volume in exchange for a larger rebate"; or (2) because a drug has "limited or inadequate evidence of clinical efficacy."⁸ Neither of these rationales advance the objectives of the Medicaid statute.

Based on the SSA's language and structure, the U.S. Department of Health and Human Services ("HHS") and the courts agree that "the core objective of the Medicaid Act is to furnish health-care coverage to the needy."⁹ Indeed, the U.S. Court of Appeals for the D.C. Circuit confirmed in 2020 that "the principal objective of Medicaid is providing health care coverage."¹⁰ Allowing a wholesale waiver of the drug coverage requirements in the rebate statute would reduce members' access to medicines and adversely affect their health in two ways: directly, by

⁵ SSA § 1115(a).

⁶ SSA § 1115(a).

⁷ SSA § 1115(a).

⁸ Application at 30-31.

⁹ See *Philbrick v. Azar*, 397 F.Supp.3d 11 (D.D.C. 2019); *Gresham v. Azar*, 363 F. Supp. 3d 165, 176 (D.D.C. 2019) (noting that the HHS Secretary "refers to the provision of medical care to eligible persons as 'Medicaid's core objective.'"); see also SSA § 1901 (describing the purpose of the Medicaid program as enabling states to furnish "medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services," as well as "rehabilitation and other services to help such families and individuals attain or retain capability for independence or self-care").

¹⁰ See *Gresham v. Azar*, 950 F.3d 93, 99 (D.C. Cir. 2020).

permitting the State to cut back on drug coverage; and indirectly, by eliminating or curtailing manufacturers' incentive to participate in the Medicaid Drug Rebate Program ("MDRP")—a program that has successfully provided Medicaid members "access to the same range of drugs that the private patients of their physicians enjoy"¹¹ since its start in 1991.

The direct damage from the waiver is also disturbing—and easy to anticipate—because the impact of closed formularies that restrict drug access for vulnerable populations has already been extensively studied. Notably, these studies show that restricting access to drugs results in non-adherence or poor adherence to prescribed medication regimens; worsened health outcomes; and higher, long-run costs, both to Medicaid and other state and local programs.¹² Medicaid patients, compared to those with other types of insurance, have higher rates of complex and chronic health conditions that often require access, without delay, to a broad range of medicines as prescribed by their physicians in order to achieve optimal therapeutic results,¹³ thereby amplifying the detrimental effects of a closed formulary.

Moreover, given how broadly the Proposed Amendment defines drugs with "limited or inadequate evidence of clinical efficacy," allowing the Medicaid formulary to exclude these drugs could deny Medicaid members access to many vital and innovative drugs. According to the Proposed Amendment, "[l]imited or inadequate clinical efficacy may be defined as when one or more of the following conditions exist:

- 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."¹⁴

The suggestion that this is a small group of medicines with doubtful benefits because, according to the Proposed Amendment, the 21st Century Cures Act ("Cures Act") expedited drug approvals "by reducing the level of evidence required for drugs to reach the market,"¹⁵ and Medicaid members will not suffer from losing access to these drugs, is incorrect. To mention just one example of the types of drugs that Oregon could exclude under the "limited or inadequate clinical efficacy" label, the last category in this list would include not just accelerated approval drugs, but *most drugs*, because FDA's drug approval framework does not require evidence of an "incremental benefit" over existing therapies for a demonstration of safety and efficacy. Drugs are approved in this country if they are shown to be safe and effective—that is what the law demands and accordingly, what FDA requires manufacturers to demonstrate.

¹¹ H.R. Rep. No. 101-881 at 96-97 (1990), reprinted in 1990 U.S.C.C.A.N. 2017, 2108-09.

¹² We summarize the research in section IV of this letter.

¹³ MACStats: Medicaid and CHIP Data Book at Exhibit 43, MACPAC (December 2019), <https://www.macpac.gov/wp-content/uploads/2015/12/MACStats-Medicaid-and-CHIP-Data-Book-December-2019.pdf>.

¹⁴ Application at 31.

¹⁵ Id.

To the extent Oregon suggests that the Cures Act amended the statutory standards for approval and coverage, these suggestions are wrong. All approved/licensed drugs are subject to the same standards of safety and efficacy for approval/licensure, and nothing in the Cures Act changed or diluted FDA's strict approval standards. Indeed, the Cures Act “ensure[s] that our country remains on the forefront of medical innovation while maintaining the gold standard for approvals of medical products.”¹⁶ In fact, research has shown that drugs approved through expedited review “offered larger health gains, compared to drugs approved through conventional review processes,”¹⁷ suggesting that FDA has prioritized drugs that offer the most significant health advances. If Oregon intended to refer to drugs approved under the accelerated approval pathway when discussing the Cures Act, as further discussed below, these drugs are subject to the same standards of safety and efficacy as all other FDA-approved drugs.

Denying Medicaid members access to these therapies would adversely affect their health—potentially in very serious and disturbing ways—and turn Medicaid into a second-class healthcare program whose members would lack the same access to treatment innovations “that the private patients of their physicians enjoy.”¹⁸ This is the opposite of promoting Medicaid objectives. In fact, HHS previously rejected the state’s request to proceed with the Prioritized List of Healthcare Services (“the List”) based on explicit cost-effectiveness ratios derived from quality-adjusted life years (“QALYs”). Among other objections, one of the major concerns that HHS cited was the potential for the List to discriminate against people with disabilities. The conclusion that Oregon’s closed formulary proposal, with an admitted focus on limiting access to innovative drugs that may warrant accelerated review from FDA, would not promote Medicaid objectives is even stronger given that the courts explicitly require consideration of “the impact of [the state’s] project on the persons’ the Medicaid Act ‘was enacted to protect.’”¹⁹

The Proposed Amendment’s impact cannot be written off as a necessary consequence of reducing Medicaid costs in order to keep the program sustainable. Under current law, states may create Medicaid formularies, but may exclude a drug from their formulary only if the drug’s labelling or certain compendia establish that the drug has no “therapeutic advantage in terms of safety, effectiveness, or clinical outcome” compared to “other drugs included in the formulary.”²⁰ Even then, the state must permit members to access otherwise-excluded drugs by following the state’s rules for prior authorization.²¹

Oregon seeks to waive these requirements, requesting to close its formulary and make coverage decisions in each therapeutic class based on whether manufacturers have offered sufficiently “favorable rebate agreements.”²² This approach is nothing more than cost-based rationing for the most vulnerable among us, and thus is starkly out of step with Section 1927’s “therapeutic advantage” requirement. Moreover, Oregon requests to presumptively exclude drugs approved by the accelerated pathway unless and until the state deems the drug’s price sufficiently

¹⁶ July 9, 2015 Congressional Record, House at E1036 (statement of Rep. Pallone).

¹⁷ James D. Chambers et al., *Drugs Cleared Through the FDA’s Expedited Review Offer Greater Gains Than Drugs Approved By Conventional Process*, 36 HEALTH AFFAIRS 1408, 1408 (2017).

¹⁸ H.R. Rep. No. 101-881 at 96-97 (1990).

¹⁹ *Wood v. Betlach*, 922 F. Supp.2d 836, 848 (D. Az. 2013) (quoting *Newton-Nations v. Betlach*, 660 F.3d 370, 381 (9th Cir. 2011)).

²⁰ SSA § 1927(d)(4)(C).

²¹ SSA § 1927(d)(4)(D). The state must, for example, respond to prior authorization requests within 24 hours. SSA § 1927(d)(5)(A).

²² Application at 30.

low or the drug's cost-effectiveness sufficiently high. The Proposed Amendment undercuts the value of drugs approved through the accelerated pathway, commenting that many of them "have not yet demonstrated actual clinical benefit and have been studied in clinical trials using only surrogate endpoints."²³ This, however, misconstrues the very purpose and nature of accelerated approval.

The Federal Food, Drug, and Cosmetic Act ("FDCA") makes clear that accelerated approval does not alter the statutory standard for new drug approval, and accelerated approval requires "substantial evidence" of clinical benefit.²⁴ Accordingly, the FDA has emphasized that accelerated approval drugs "meet FDA standards for safety and efficacy" and "must meet the same statutory standard for approval" as all other FDA-approved drugs.²⁵ The standard of evidence thus does not change; only the type of evidence that is evaluated differs from traditional approval. Accelerated approval permits FDA to approve drugs for a "serious or life-threatening condition" based on a determination that the drug has an effect on a surrogate or other endpoints that is "*reasonably likely to predict* clinical benefit."²⁶ Indeed, research has shown that drugs approved through the accelerated pathway "offered larger health gains, compared to drugs approved through conventional review processes."²⁷ This suggests that accelerated approval has expedited the availability of drugs that offer substantial health gains. Denying Medicaid members access to these therapies would adversely affect their health—potentially in very serious and disturbing ways—and would send the message that Medicaid is a second-class healthcare program.

Moreover, the proposal does not explain how drug costs will be assessed or how formulary decisions will be made, depriving the public of a meaningful opportunity to comment on Oregon's proposed changes to a program that has long protected access to medically necessary drugs. Oregon merely states that it "will ensure pharmacy protections for members, so that Oregon's closer management of pharmacy costs does not negatively impact member access to the spectrum of safe and effective drugs to treat various conditions."²⁸ This open-ended and ill-defined promise is not sufficient to guard against the harms presented by a closed formulary.

Section 1115 allows states to enact many types of program adjustments, including policies that may limit coverage in some respects, as long as the demonstration advances Medicaid objectives. *What states cannot do, however, is "prioritize[] program savings" without even acknowledging—much less weighing—"the consequences of lost coverage."*²⁹ To the contrary, the state and the Secretary of HHS ("Secretary") "must obviously consider the impact" of the state's proposed demonstration on the individuals that Medicaid "was enacted to protect."³⁰ And

²³ Id. at 31.

²⁴ Federal Food, Drug, and Cosmetic Act ("FDCA") § 506(e)(2) (referencing FDCA § 505(d)).

²⁵ Janet Woodcock & Peter Marks, Delivering Promising New Medicines Without Sacrificing Safety and Efficacy, FDA (last modified Aug. 27, 2019), <https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/delivering-promising-new-medicines-without-sacrificing-safety-and-efficacy>.

²⁶ FDCA § 506(c) (emphasis added); Accelerated Approval, FDA (last modified Jan. 4, 2018), <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/accelerated-approval>.

²⁷ See James D. Chambers et al., Drugs Cleared Through the FDA's Expedited Review Offer Greater Gains Than Drugs Approved By Conventional Process, 36 HEALTH AFFAIRS 1408, 1408 (2017).

²⁸ Application at 32.

²⁹ *Stewart v. Azar*, 366 F. Supp. 3d 125, 149 (D.D.C. 2019) (emphasis added).

³⁰ *Newton-Nations v. Betlach*, 660 F.3d 370, 380 (9th Cir. 2011).

in this case, the impact cannot reasonably be written off as a necessary consequence of reducing Medicaid costs in order to keep the program sustainable.

The summary of research on the effects of formulary restrictions on vulnerable populations in sections III and IV of this letter shows that these restrictions are actually likely to *increase* these members' total healthcare costs, as the savings from curbing access to drugs are typically offset (or more than offset) by increased costs of hospitalizations, emergency room visits, physician visits, and other non-drug costs. Moreover, these unintended, but predictable, consequences must be factored into decisions about whether hoped-for savings from benefit cuts are actually likely to materialize and help to promote Medicaid sustainability—or instead to backfire and hurt members' health without generating overall Medicaid savings.³¹

Congress enacted the Medicaid rebate statute to ensure that members would “have access to the same range of drugs that the privately insured patients of their physicians enjoy.”³² Oregon's request for a closed formulary would undermine this vision, especially with respect to new drugs approved under the accelerated pathway. Oregon's proposal “hinders the provision of health coverage to the needy” by jeopardizing Medicaid members' access to care and putting them on unequal footing with their counterparts in private plans or in Medicare.³³ The proposal is thus contrary to the objectives of the Medicaid statute.

B. The Medicaid Rebate Statute Is a Package Deal that Cannot Be Torn Apart by a Selective Waiver of Its Coverage Requirements Alone

Although the Proposed Amendment does not indicate whether the state is willing to give up the statutory Medicaid rebates it currently receives under Section 1927 of the SSA, Oregon's request for a closed formulary seeks to waive Section 1927 via a waiver of Section 1902(a)(54), to allow exclusion of covered outpatient drugs broadly, as well as “drugs with limited or inadequate evidence of clinical efficacy,” including accelerated approval drugs specifically.³⁴ We thus understand Oregon to be seeking continued manufacturer rebates under federal law (in addition to any supplementary rebates negotiated by the state) despite excluding drugs from coverage. This request for a waiver of drug coverage requirements under Section 1927(d)(4), without also waiving the state's access to mandatory rebates under the MDRP, is flatly inconsistent with the Medicaid rebate statute.

The Centers for Medicare & Medicaid Services (“CMS”) cannot waive the Medicaid rebate statute's coverage requirements while leaving in place the requirement for manufacturers to pay rebates on Medicaid utilization. Such a one-sided waiver would breach the careful legislative

³¹ See, e.g., *Wood v. Betlach*, 992 F. Supp. 836, 850 (D. Ariz. 2013) (finding that CMS acted arbitrarily and capriciously in approving an 1115 demonstration increasing beneficiary copayments where a declaration that plaintiffs submitted to CMS showed that “extensive research on cost sharing for the poor has shown that copayments are not an effective Medicaid cost-saving measure for states” due to higher drug copayments leading members to use fewer drugs and more emergency room and inpatient hospital care, but CMS “made [no] effort to address Plaintiffs' administrative objections that copayments are not an effective cost-saving measure”).

³² H.R. Rep. No. 101-881 at 96-97 (1990) (emphasis added).

³³ See *Gresham v. Azar*, 363 F. Supp. 3d 165, 178 (D.D.C. 2019).

³⁴ Application at 30-31.

bargain Congress created in the Medicaid rebate statute, described by Congressman Henry Waxman, a key sponsor, as a “government-industry compact.”³⁵ As CMS has explained:

[D]rug manufacturers must pay statutorily-defined rebates to the states through the Medicaid drug rebate program. In return, any state that provides payment for drugs must cover all covered outpatient drugs, which may include appropriate limitations on amount, duration, and scope, for the drug manufacturers that participate in the Medicaid drug rebate program.³⁶

The rebate statute’s legislative history similarly emphasizes that the statute links manufacturer rebate obligations and Medicaid coverage obligations:

The Committee believes that Medicaid, the means-tested entitlement program that purchases basic health care for the poor, should have the benefit of the same discounts on single source drugs that other large public and private purchasers enjoy. The Committee bill would therefore establish a rebate mechanism in order to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser. Because the Committee is concerned that Medicaid beneficiaries have access to the same range of drugs that the private patients of their physicians enjoy, the Committee bill would require states that elect to offer prescription drugs to cover all of the products of any manufacturer that agrees to provide price rebates.³⁷

Congress thus required states to cover all products of a manufacturer with a Medicaid rebate agreement (with specified exceptions), to ensure member access to the full range of drugs that are available to privately insured patients. Accordingly, the statute purposely coupled the rebate requirements on manufacturers with the coverage requirements on states. The standard Medicaid Rebate Agreement between CMS and each manufacturer that participates in the MDRP also emphasizes this bargain: it details manufacturers’ obligations to calculate and pay rebates, and recognizes that manufacturers must be able to rely on states fulfilling their end of the statutory bargain (and to enlist CMS’s assistance if a state does not fulfill its coverage obligations).³⁸

As the Supreme Court has emphasized, “strict adherence to the language and structure of [an] Act is particularly appropriate where . . . a statute is the result of a series of carefully crafted compromises.”³⁹ Many cases similarly hold that when a statute reflects a legislative bargain, it

³⁵ Medicare and Medicaid Reconciliation: Hearings Before the Subcomm. on Health and the Environment of the Committee on Energy and Commerce, H. Hrg. 103-61, 103rd Cong. 453 (1993) (statement of Rep. Waxman).

³⁶ 78 Fed. Reg. 4594, 4631 (Jan. 22, 2013) (emphasis added). The rebate statute’s legislative history similarly emphasizes this compact: “Because the Committee is concerned that Medicaid beneficiaries have access to the same range of drugs that the private patients of their physicians enjoy, the Committee bill would require States that elect to offer prescription drugs to cover all of the products of any manufacturer that agrees to provide price rebates.” H.R. Rep. No. 101-881 at 96-97 (1990) (emphasis added).

³⁷ H.R. Rep. No. 101-881 at 96-97 (1990) (emphasis added).

³⁸ Medicaid Rebate Agreement § VI(a) (“A State’s failure to comply with the drug access requirements of section 1927 of the Act shall be cause for the Manufacturer to notify CMS and for CMS to initiate compliance action against the State under section 1904 of the Act [establishing a notice and hearing process for CMS to stop or reduce payments to State Medicaid programs that are out of compliance with their State plan obligations]”).

³⁹ *Community for Creative Non-Violence v. Reid*, 490 U.S. 730, 748 n.14 (1989).

must be interpreted to uphold that bargain, not tear it asunder.⁴⁰ Applying this principle here, the rebate statute is a package—with benefits and obligations for both manufacturers and Medicaid—and CMS cannot authorize a state to keep the benefits of the package, but jettison its coverage responsibilities. The Proposed Amendment that Oregon seeks—which would expand its power to restrict coverage—would thwart the core objective of the rebate statute, undermining the compact between states and manufacturers.

CMS fully recognizes this statutory compact, as demonstrated by its decision to deny a Section 1115 waiver amendment request from Massachusetts to establish a closed formulary and exclude coverage of “accelerated approval pathway” drugs.⁴¹ On June 27, 2018, CMS rejected this part of Massachusetts’s request on the grounds that it “would have allowed the State to continue to collect manufacturer rebates under Section 1927, while enabling the state to exclude certain drugs from coverage,” thereby rupturing the statute’s careful balance.⁴² That same day, CMS issued a Program Notice emphasizing that Medicaid programs may not exclude coverage for a drug merely because it was approved under FDA’s accelerated pathway. By definition, these are “drugs for serious conditions that fill an unmet medical need,” which have, to FDA’s satisfaction, shown promising results on surrogate or intermediate clinical endpoints that are “reasonably likely to predict a real clinical benefit.”⁴³ A drug that has received FDA approval, accelerated or otherwise, “meets the definition of [a] covered outpatient drug” under Section

⁴⁰ See, e.g., *General Motors Corp. v. Romein*, 503 U.S. 181, 191 (1992) (upholding statutory provisions necessary to “preserve the delicate legislative compromise that had been struck by [prior] laws”); *Mohasco Corp. v. Silver*, 447 U.S. 807, 826 (1980) (“We must respect the compromise embodied in the words chosen by Congress. It is not our place simply to alter the balance struck by Congress . . .”); *Rodriguez v. Compass Shipping Co.*, 451 U.S. 596, 612 (1981) (“[In] interpreting the intent of Congress in fashioning various details of this legislative compromise, the wisest course is to adhere closely to what Congress has written”); *Villarreal v. R. J. Reynolds Tobacco Co.*, 839 F.3d (11th Cir. 2016) (elevating general notions of purpose over statutory text “disregards the processes of [legislative compromise] and, in the end, prevents the effectuation of congressional intent”) (citation omitted); *United States v. Taylor*, 487 U.S. 326, 336 (1988) (“the purposes of the Act and the legislative compromise it reflects [must be] given effect”); *American Mining Congress v. EPA*, 824 F.2d 1177, 1187 (D.C. Cir. 1987) (courts “must be loathe to tear asunder” the process of legislative compromise).

⁴¹ MassHealth Section 1115 Demonstration Amendment Request (Sept. 8, 2017), <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ma/ma-masshealth-pa3.pdf>. PhRMA notes that on January 8, 2021, despite having rejected the Massachusetts closed formulary request in 2018, CMS approved a Medicaid demonstration amendment from Tennessee that authorized the use of a closed formulary. See CMS Demonstration Approval: TennCare III (Project Number 11- W-00369/4), CMS (as amended Jan. 20, 2021), <https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/tn-cms-aprvl.pdf>. As detailed in PhRMA and many stakeholder comments to CMS on Tennessee’s demonstration amendment, CMS does not have the legal authority under the SSA to approve the Tennessee amendment. PhRMA’s Comments on Tennessee’s “TennCare III” Medicaid Demonstration (Project Number 11-W-00369/4), https://1115publiccomments.medicaid.gov/jfe/file/F_3DkgKMhfPUCv6Gh. CMS has since reopened implementation of the demonstration amendment in response to litigation involving the approval and solicited a new round of public comments on the amendment. See *McCutchen et al v. Becerra et al*, No. 21-cv-01112, Government’s Unopposed Motion to Hold in Abeyance (D.D.C. Aug. 11, 2021) (asking to hold the case in abeyance while CMS “opens the federal comment period on the Medicaid demonstration approval challenged in this lawsuit and reconsiders the challenged decision.”); CMS, 1115 TennCare III - Approval STCs, https://1115publiccomments.medicaid.gov/jfe/form/SV_9zWXfvSDSRtLxAy.

⁴² Letter from Tim Hill, Acting Director, Ctr. for Medicaid & CHIP Services, to Daniel Tsai, Assistant Sec’y, MassHealth, at 2 (June 27, 2018) [hereinafter “CMS Response to Massachusetts”], <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ma/MassHealth/ma-masshealth-demo-amndmnt-appvl-jun-2018.pdf>.

⁴³ Accelerated Approval, FDA (last modified Jan. 4, 2018), <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/accelerated-approval>; see also 21 U.S.C. § 356(c).

1927(k), meaning that “the drug must be covered by state Medicaid programs if the manufacturer has an applicable signed Medicaid national drug rebate agreement.”⁴⁴

C. A Closed Formulary Is Not a Permissible “Experimental, Pilot, or Demonstration Project” Under Section 1115

Section 1115 authorizes the Secretary to approve “experimental, pilot, or demonstration project[s].”⁴⁵ Approved demonstrations must not only serve the objectives of the Medicaid program, but must also be designed and intended to learn and/or demonstrate something new. Oregon’s proposal fails to specify how it will serve as an “experimental” or “demonstration” project as required under Section 1115. The Proposed Amendment appears to propose using a closed formulary as a cost-cutting measure without associated research metrics to determine if such a change would further the core objectives of the Medicaid programs, which is not permissible under Section 1115.

As the courts have explained,

[t]he purpose of these [Section 1115] demonstrations, which give states additional flexibility to design and improve their programs, is to *demonstrate and evaluate policy approaches* such as: expanding eligibility to individuals who are not otherwise Medicaid or CHIP eligible; providing services not typically covered by Medicaid; using innovative service delivery systems that improve care, increase efficiency . . .⁴⁶

Similarly, as the Ninth Circuit explained in *Beno v. Shalala*:

[SSA § 1115] requires that the state project be an experimental, demonstration or pilot project. *The statute was not enacted to enable states to save money or to evade federal requirements* but to test out new ideas and ways of dealing with the problems of public welfare recipients. Thus, the Secretary must make some judgment that the project has a research or a demonstration value. *A simple benefits cut, which might save money, but has no research or experimental goal, would not satisfy this requirement . . .* the Secretary must make at least some inquiry into the merits of the experiment—she must determine that the project is likely to yield useful information or demonstrate a novel approach to program administration.⁴⁷

The Ninth Circuit applied this reasoning in *Newton-Nations v. Betlach* and found CMS’s approval of an Arizona demonstration increasing Medicaid copayments to be arbitrary and capricious.⁴⁸ Notably, the court questioned whether the initiative could have research or demonstration value given that “Plaintiffs’ public health expert stated that over the last 35 years,

⁴⁴ Medicaid Drug Rebate Program Notice, State Medicaid Coverage of Drugs Approved by the FDA under Accelerated Approval Pathway, CMS (June 27, 2018), <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-185.pdf> (emphasis added).

⁴⁵ SSA § 1115(a).

⁴⁶ See *Nazareth Hosp. v. Sec’y U.S. Dep’t of Health & Human Servs.*, 747 F.3d 172, 181 (3d Cir. 2014) (emphasis added); *Cooper Hosp. / Univ. Med. Ctr. v. Burwell*, 179 F. Supp. 3d 31, 50 (D.D.C. 2016), *aff’d sub nom. Cooper Hosp. Univ. Med. Ctr. v. Price*, No. 16-5165, 2017 WL 2347695 (D.C. Cir. May 9, 2017) (quoting the Third Circuit).

⁴⁷ *Beno v. Shalala*, 30 F.3d 1057, 1069 (9th Cir. 1994).

⁴⁸ *Newton-Nations v. Betlach*, 660 F.3d 370, 381 (9th Cir. 2011).

a number of studies have looked at the effects of cost sharing on the poor” and that “[t]he administrative record contains no finding from the Secretary that Arizona’s demonstration project will actually demonstrate something different than the last 35-years’ worth of health policy research.”⁴⁹

A large body of research exists on how restrictions affect vulnerable populations, similar to the cost-sharing research cited in *Newton-Nations*. The topic has already been extensively studied. Section IV of this letter provides a detailed summary of that body of research—which shows that imposing formulary restrictions on vulnerable populations generally produces adverse effects on members’ health; increases the risks of justice system contacts and other social problems; and increases overall healthcare costs, as beneficiary care increasingly shifts from outpatient drugs to hospitalizations and emergency room visits.

Nothing in the Proposed Amendment suggests that the requested waiver would advance knowledge of the impact limiting access to medicines for the needy. The most this demonstration could possibly achieve would be to replicate the negative outcomes found in the existing literature. This is not research, but a “simple benefits cut,”⁵⁰ with a wholly predictable outcome, and is therefore inconsistent with Section 1115’s purpose.

D. The Demonstration Amendment Lacks Sufficient Detail to Provide a Meaningful Opportunity for Public Comment

Following years of concern about the transparency of Section 1115 demonstration approvals, the Affordable Care Act amended Section 1115 to require greater transparency and opportunity for public comment relating to proposed demonstrations that would affect “eligibility, enrollment, benefits, cost-sharing, or financing.”⁵¹ Pursuant to this mandate, CMS issued regulations requiring a public notice and comment process at the state and federal levels meeting basic transparency standards specified in the regulations. Oregon has, in accordance with those regulations, released a draft Application for public comments, which includes the Proposed Amendment. The Application leaves out crucial details, however, and thus fails to satisfy the requirement for a “comprehensive description of the demonstration application or extension to be submitted to CMS that contains a sufficient level of detail to ensure meaningful input from the public.”⁵²

In several important areas, Oregon has provided only vague outlines of the Proposed Amendment. These rough sketches are insufficient for the public to understand the state’s intentions or to provide “meaningful” comments on the proposal’s risks and benefits. The following are only some of the many examples of underspecified proposal elements:

- 42 C.F.R. § 431.408 requires a “hypothesis and evaluation parameters of the demonstration,” and Oregon’s Proposed Amendment clearly falls short of this requirement.⁵³ While Oregon offers hypotheses for the other changes proposed in the

⁴⁹ Id. at 381 (emphasis added).

⁵⁰ *Beno v. Shalala*, 30 F.3d at 1069.

⁵¹ SSA § 1115(d)(1).

⁵² 42 C.F.R. § 431.408(a)(1)(i).

⁵³ Id. § 431.408(a)(1)(i)(D).

Application, it offers no hypotheses or evaluation parameters for the impact the Proposed Amendment.

- More explanation is needed of the statement that Oregon “will ensure pharmacy protections for members, so that Oregon’s closer management of pharmacy costs does not negatively impact member access to the spectrum of safe and effective drugs to treat various conditions.”⁵⁴ This brief statement is less than a “comprehensive description” of the initiative that “contains a sufficient level of detail to ensure meaningful input from the public,” as Oregon provides no explanation of the types of protections it envisions to ensure access to safe and effective drugs.⁵⁵
- The description of how the closed formulary would be developed and the types of drugs that could be excluded (e.g., drugs labeled as having “limited or inadequate clinical efficacy” or an even broader group) is also insufficient to ensure meaningful public input. Oregon states only that it will “use its own rigorous review process to determine coverage of new drugs and to prioritize patient access to clinically proven, effective drugs,”⁵⁶ but describes nothing further about what that rigorous review process would entail.
- We are further concerned that the listing of drug categories ostensibly having “limited or inadequate clinical efficacy” actually includes a broad and vitally important group of drugs, and the description of these drugs in the Proposed Amendment may cause confusion about the scope of potential formulary exclusions and thereby prevent meaningful stakeholder comments on the closed formulary proposal.

II. Cost Containment Tools to Control Pharmacy Expenditures are currently Available Under Section 1927 and Other Provisions

In exchange for substantial guaranteed rebates, state Medicaid programs must cover most outpatient drugs with certain statutory exceptions. States have access to numerous cost containment tools to control or manage access and encourage responsible and cost-effective use of medicines within the Medicaid program. In 2019, Medicaid prescription drug spending in Oregon was found to be only 3.3% of total Medicaid spending, due in part to manufacturer rebates and other cost containment tools.⁵⁷ If Oregon seeks increased leverage to negotiate higher rebates from manufacturers, Oregon should use the cost containment tools available under the drug rebate statute before taking such drastic action to remove drugs from coverage.

Section 1927 already offers multiple policy levers through which states can control inappropriate drug utilization and reduce drug spending. Among other tools, states have the authority to exclude a drug from their formulary if the drug’s labelling or certain compendia establish that the drug has no “therapeutic advantage in terms of safety, effectiveness, or clinical outcome” compared to “other drugs included in the formulary.”⁵⁸ In view of this existing authority,

⁵⁴ Application at 32.

⁵⁵ See 42 C.F.R. § 431.408(a)(1)(i); Application at 32.

⁵⁶ Application at 31.

⁵⁷ The Facts About Medicaid in Oregon, PhRMA, https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/Medicaid-2019/OR-One-Pager_19.pdf.

⁵⁸ SSA § 1927(d)(4)(C).

Oregon’s request for a closed formulary suggests an intent to exclude coverage for medications that *do* have a “therapeutic advantage” over other drugs.

In outlining the parameters for prescription drug coverage in the Medicaid program, Congress enacted comprehensive provisions designed to protect patients. If Oregon wants to establish a formulary, it should do so through existing authority in the Medicaid drug rebate statute. Yet it has chosen not to do so. Instead, the Proposed Amendment seeks to create a “closed formulary” that would exclude a wide range of drugs without making the clinical determinations required under the SSA, effectively vitiating formulary safeguards established by Congress for the protection of members. Doing so is not “likely to assist in promoting the objectives of title XIX” of the SSA and fails to meet a basic requirement of Section 1115.⁵⁹

The cost containment tools available to states under SSA §1927 include the following:

- States may impose prior authorization requirements on any drug, provided they respond to prior authorization requests within 24 hours and dispense a 72-hour supply of the requested drug in an emergency;⁶⁰
- States may exclude or restrict coverage of any drug that is not prescribed for a “medically accepted indication” (defined as FDA-approved indications plus off-label uses supported by specified compendia);⁶¹
- States may impose restrictions authorized by an agreement with the drug manufacturer, also known as the Medicaid Drug Rebate Agreement;⁶²
- States may exclude or restrict coverage of any drug used for certain listed purposes (e.g., anorexia, weight loss, weight gain, to promote fertility, for cosmetic purposes, etc.);⁶³
- States may create Medicaid formularies and exclude a drug from a Medicaid formulary if: (a) the drug’s labeling or certain compendia establish that the drug “does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome” over a drug included on the formulary, (b) there is a publicly-available written explanation of the basis for the exclusion, (c) the excluded drug is available with prior authorization, and (d) certain additional requirements relating to the committee that develops the formulary are satisfied;⁶⁴
- States “may impose limitations, with respect to all . . . drugs in a therapeutic class, on the minimum or maximum quantity per prescription or on the number of refills, if . . . necessary to discourage waste, and may address instances of fraud or abuse by individuals in any manner authorized under [the Medicaid statute];”⁶⁵ and

⁵⁹ SSA § 1115(a).

⁶⁰ SSA § 1927(d)(1)(A),(5).

⁶¹ SSA § 1927(d)(1)(B)(i).

⁶² SSA § 1927(d)(1)(B)(iii).

⁶³ SSA § 1927(d)(1)(B)(ii),(2).

⁶⁴ SSA § 1927(d)(4).

⁶⁵ SSA § 1927(d)(6).

- States may create PDLs, which are lists of drugs that are not subject to prior authorization and are not “formularies” that must satisfy the rebate statute’s requirements for formularies, and may demand supplemental rebates as the price for including a drug on the PDL.⁶⁶

The leverage provided to states by these measures is so great that as of June 2021, 47 states (including Oregon) and the District of Columbia had supplemental rebate programs that allowed them to collect extra rebates above and beyond the large rebates required by the rebate statute.⁶⁷

Oregon may also rely on voluntary, value-based payment arrangements for Medicaid drug purchasing. Value-based arrangements can improve member outcomes, reduce medical costs, and reduce the cost of medicines. These arrangements can improve member access to medicines while supporting better health outcomes and reducing hospitalizations and other medical costs. Value-based contracting arrangements should be tailored carefully to address the medication involved and the members and disease conditions they seek to treat. Such arrangements have already been explored in other states including Colorado⁶⁸, and Michigan,⁶⁹ and are currently being implemented in Oklahoma,⁷⁰ Washington,⁷¹ and Louisiana.⁷² Value-based agreements for Medicaid members must be voluntary, however, given that a statutory minimum rebate is already in place. In other words, the arrangements must be effected through a supplemental rebate agreement. Voluntary, value-based agreements could include:⁷³

- Outcomes-based arrangements, which tie costs or discounts to member outcomes;
- Conditional treatment continuation arrangements, which typically are conditioned on meeting short-term treatment goals;
- Indication-based pricing arrangements, where the net price varies based on the indication for treatment;

⁶⁶ PhRMA v. Meadows, 304 F.3d 1197 (11th Cir. 2002); PhRMA v. Thompson, 362 F.3d 817, 823-24 (D.C. Cir. 2004).

⁶⁷ Medicaid Pharmacy Supplemental Rebate Agreements, CMS (June 2021), <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/xxxsupplemental-rebates-chart-current-qtr.pdf>.

⁶⁸ “CMS Oks Colorado’s waiver for Medicaid value-based purchasing”. Modern Healthcare, (February 2019) <https://www.modernhealthcare.com/article/20190225/NEWS/190229950/cms-oks-colorado-s-waiver-for-medicaid-value-based-purchasing>

⁶⁹ Nicholas Fiore et al. *Novel State Payment Models for Prescription Drugs: Early Implementation Successes and Challenges*. Duke Margolis Center for Health Policy, (September 2019). <https://healthpolicy.duke.edu/sites/default/files/2020-07/Novel%20State%20Payment%20Models%20Final%20Revised%20091219.pdf>

⁷⁰ Reck, Jennifer. Oklahoma Signs the Nation’s First State Medicaid Value-Based Contracts for Rx Drugs, National Academy for State Health Policy (NASHP) (September 25, 2018). <https://www.nashp.org/oklahoma-signs-first-medicaid-value-based-contracts-for-rx-drugs/>

⁷¹ “AbbVie Wins Hep C contract with Washington State in Latest ‘Netflix’ Deal,” BioPharma Dive, April 26, 2019. <https://www.biopharmadive.com/news/abbvie-wins-hep-c-contract-with-washington-state/553576/>

⁷² Gee, Rebekah. *Louisiana’s Journey Toward Eliminating Hepatitis C*, Health Affairs Blog, (April 1, 2019).

⁷³ Comer, Ben. “Six Drug Pricing Models Have Emerged to Improve Product Access and Affordability.” PwC, (September 2019). <https://www.pwc.com/us/en/industries/health-industries/library/6-drug-pricing-models.html>.

- Regimen-based pricing arrangements, where the net price of a medicine decreases when a member must take additional medication to make the treatment more effective; and
- Expenditure cap arrangements, which limit the cost of medicine per member to a negotiated threshold.⁷⁴

The availability of a wide array of alternative cost containment mechanisms, many of which are being explored in other states, demonstrates that Oregon's proposed authorization for a closed formulary is fiscally unnecessary, in addition to being harmful to OHP members.

III. Restricting Medicaid Drug Coverage Would Exacerbate Existing Health Inequities

Since the start of the COVID-19 pandemic, roughly one in four Americans have been laid off or lost their job due to the pandemic. Financial insecurity during this time has affected the ability of many to pay for necessities, with 44% of respondents stating in a recent poll that they have used money from savings/retirement to pay bills, and 35% stating that they have received food from a food bank/organization since the start of the pandemic.⁷⁵ The economic instability brought on by the pandemic has increased Medicaid rolls nationwide. Oregon's Medicaid program has experienced a 24.16% jump in enrollment (+260,000 members) since March 2020, and it is estimated that over 300,000 current members may lose eligibility during the redetermination process once federal pandemic Public Health Emergency provisions expire.⁷⁶

Due to concerns about the pandemic, 41% of adults have avoided or delayed routine or emergency/urgent care.⁷⁷ The prevalence of delaying or avoiding care is higher among Black (60% higher) and Hispanic (50% higher) adults than non-Hispanic White adults and higher still among indigenous populations. These disparities demonstrate that the pandemic has had harmful effects on the social, economic, and health care-related outcomes among lower-income and racially/ethnically-diverse groups.

Predating the COVID-19 pandemic, there have been myriad longstanding and intersecting systemic, social, and structural barriers that have impeded equitable access to medicines. Research clearly shows that social determinants of health impact life-long health care outcomes.⁷⁸ Additionally, patients respond differently to treatment because of a number of factors, such as genetics, age, sex, socioeconomic status, drug-drug interactions, diet, environment, and co-

⁷⁴ Trusheim MR, Cassidy WM, Bach PB. Alternative State-Level Financing for Hepatitis C Treatment—The “Netflix Model”. *JAMA*. 2018;320(19):1977–1978.

⁷⁵ Hamel L, Lopes L, Munana C, Artiga S. KFF/The Undeclared Survey on Race and Health. Kaiser Family Foundation. Oct 2020. <https://www.kff.org/report-section/kff-the-undeclared-survey-on-race-and-health-main-findings/#ExecutiveSummary>.

⁷⁶ <https://stateofreform.com/featured/2021/10/oha-says-as-many-as-300000-enrollees-may-come-off-the-oregon-health-plan-once-the-public-health-emergency-ends/>.

⁷⁷ Czeisler MÉ, Marynak K, Clarke KE, et al. Delay or Avoidance of Medical Care Because of COVID-19–Related Concerns — United States, June 2020. *MMWR Morb Mortal Wkly Rep* 2020;69:1250–1257.

⁷⁸ Reno R, Warming E, Zaugg C, Marx K, Pies C. Lessons Learned from Implementing a Place-Based, Racial Justice-Centered Approach to Health Equity. *Matern Child Health J*. 2021 Jan;25(1):66-71.

morbidities. This means that treatments that are the best option for some individuals are not as effective for others.⁷⁹

In addition, underserved populations are often treated later for many diseases, such as certain cancers⁸⁰ and asthma. Therefore, timely access to provider-recommended medicines is central to reversing that trend, improving health outcomes, decreasing avoidable health care utilization and costs,⁸¹ and reducing mortality.

As such, Oregon's Proposed Amendment to implement a closed formulary would not serve the state's other laudable goals of advancing health equity. Instead, it would curtail any bridging of health care gaps by creating yet another layer of bureaucracy, impeding equitable access to necessary medications. A recent study suggests that restrictive benefit designs are associated with reduced medication adherence and negative clinician outcomes.⁸² Moreover, a restrictive, closed formulary would undervalue patient preferences and medication needs made in consultation with their physicians and the priorities and health care needs of diverse populations in Oregon. As a result, patients with chronic and other conditions may lose access to their current treatments or experience disruptions in care.

America's biopharmaceutical companies maintain frontline commitment to developing more treatments and vaccines not just for COVID-19, but also for thousands of other debilitating and life-threatening conditions including those like Alzheimer's disease,⁸³ certain cancers,^{84,85} and many other common chronic and rare diseases. There are a number of conditions disproportionately impacting communities of color, including sickle cell disease and metachromatic leukodystrophy in African American and Hispanic populations, and lupus and sarcoidosis across indigenous communities. Patients of color with rare diseases face extraordinary challenges and experience a disproportionate burden in accessing care.

The state's proposed intent to exclude from its formulary drugs "with limited or inadequate evidence of clinical efficacy" is especially problematic with respect to the assignment of "value" of medicines. Measurements accounting for "clinical efficacy" often obscure the distinct needs of disadvantaged populations, including communities of color, by rendering judgments about value based on "average" study results, which often reflect primarily White populations and ignore diversity in preferences and other factors that impact health, such access to care, education, and literacy.

⁷⁹ McRae, J., Onukwugha, E. Why the Gap in Evaluating the Social Constructs and the Value of Medicines?. *PharmacoEconomics* (2021).

⁸⁰ Halpern MT, Holden DJ. Disparities in timeliness of care for U.S. Medicare patients diagnosed with cancer. *Curr Oncol*.2012;19(6):e404-e413.

⁸¹ Sokol MC, McGuigan KA, Verbrugge RR, Epstein RS. Impact of medication adherence on hospitalization risk and healthcare cost. *Med Care*. 2005 Jun;43(6):521-30.

⁸² Park Y, Raza S, George A, Agrawai R, Ko J. The Effect of Formulary Restrictions on Patient and Payer Outcomes: A Systematic Literature Review. *JMCP*. August 2017; 23 (8). <https://www.jmcp.org/doi/pdf/10.18553/jmcp.2017.23.8.893>.

⁸³ 2020 Alzheimer's disease facts and figures. *Alzheimer's and Dementia*. <https://alz-journals.onlinelibrary.wiley.com/doi/full/10.1002/alz.12068>.

⁸⁴ Cancer Stat Facts: Prostate Cancer. SEER. <https://seer.cancer.gov/statfacts/html/prost.html>

⁸⁵ Multiple Myeloma Research Foundation. <https://themmr.org/multiple-myeloma/black-patients/>.

For example, the value of a lifesaving treatment for Black patients can be automatically valued up to 10% less than for White patients due to biased value metrics such as the quality-adjusted life year or QALY.⁸⁶ Most Medicaid patients contend with chronic and rare disease management that requires regular assessments by a provider to determine the type of medicine and dosage that works best. Anything other than an open formulary, free from value constraints, runs the risk of ignoring important patient differences and overriding physician-patient decisions about the best course of treatment for any patient population, but most especially for those served by Medicaid.

Implementing a closed formulary could have the unintended consequence of widening health disparities at a time when Oregon residents are still dealing with the continued effect of the pandemic, and previous and possible pandemic-induced health conditions.

We applaud the state on its other proposals in the amendment to improve health equity, which may be more effective at improving health equity than a closed formulary. Such other measures include improvement of quality metrics and data collection and reporting designed to incentivize systems-level changes that advance equity and address domains for which no current metrics exist. The COVID-19 pandemic has underscored disparate data collection and reporting practices across states and even by the federal government. A key opportunity to improve health outcomes among Oregon's Medicaid population is to promote standards in the collection and reporting of data, including social determinants of health data, that can be applied across the health system, using granular definitions to reflect diversity within broad categories of race and ethnicity, ensuring data collection in a culturally sensitive manner, while safeguarding against misuse of personally identifiable data.

We recommend that improvements in data collection and reporting involve strong engagement with experts, community leaders (e.g., historically black colleges and universities and community health centers), and patients themselves to understand and test which social determinants of health data are most important to collect, and in what manner to collect them. We also encourage efforts to collect and use health data to consider the intersection between different social and demographic factors. Many populations experience more than one source of disadvantage at a time which can have multiplicative impacts on an individual's life experiences.⁸⁷

Additionally, there are opportunities to leverage existing data to better inform health care use and outcomes across important subpopulations, particularly as they relate to health disparities. For example, CMS publicly reports select information to inform health disparities among the Medicare and Medicaid populations that could be readily expanded to better understand inequities in diagnosis and treatment by adding measures of recommended screenings and use of medicines.

We also applaud the state's intent to collaborate with community-based organizations on strategies to improve health equity. We have mutual interest in empowering traditional and non-traditional, community-based partners to align with the health sector towards addressing health

⁸⁶ Broder, M, Ortendahl, J. Is Cost-Effectiveness Analysis Racist? Partnership for Health Analytic Research. 2021. <https://blogsite.healthconomics.com/2021/08/is-cost-effectiveness-analysis-racist/>.

⁸⁷ Nick G, Schloss K, Lekas HM, et al. A Social Determinants Perspective of the Intersection of Ageism, Racism, and Social Isolation During COVID-19. Behavioral Health News. Jan 1, 2021. <https://behavioralhealthnews.org/a-social-determinants-perspective-of-the-intersection-of-ageism-racism-and-social-isolation-during-covid-19/>.

inequity and social determinants of health across the continuum, from birth to adulthood. Community-based organizations are integrated with and understand the specific needs of the communities they serve, which is critical to successfully engaging and reaching underserved areas. These organizations can recommend approaches most likely to resonate with their communities.

In April 2019, PhRMA created the Collaborative Actions to Reach Equity (“CAREs”) grant program, which has since awarded nearly \$400,000 to community organizations, institutions, and individuals who have a mission to advance health equity. The PhRMA CAREs grant program aims to address health inequities through partnership with community-led organizations to support local and national activities and research, driving meaningful change on the ground by addressing pressing issues, such as maternal mortality, access to COVID-19 treatments and vaccines, disparities in medication use/access, and bias in seeking health care.

Bridge-Pamoja, a CAREs grant recipient located in Portland, Oregon,⁸⁸ is a network of faith-based leaders and culturally specific organizations dedicated to addressing unique needs of African and African American communities through grassroots and community-based efforts. To combat the COVID-19 pandemic, Bridge-Pamoja aims to break down barriers to the uptake of COVID-19 vaccines within local African and African American communities using a three-pronged approach: 1) partnering with state officials to track how many Africans and African Americans successfully complete doses of COVID-19 vaccines; 2) monitoring how the state government partners with Black-led organizations (including houses of worship) to perform outreach to the African and African American communities regarding COVID-19 vaccination; and 3) hosting virtual forums with Black community and faith leaders to address the successes and challenges of the state’s COVID-19 vaccination outreach process.⁸⁹ Through these efforts, Bridge-Pamoja has helped to create an environment that fosters relationships of trust through reliable messengers.

This is just one example of the type of impact on-the-ground organizations can have to improve health equity. As the state continues to consider meaningful actions to improve health equity, we are happy to discuss solutions to a shared goal in addressing health equity—solutions that do not impair access to necessary and much-needed medicines for Medicaid patients, but that promote and provide opportunities to thrive.

IV. The Proposed Amendment Ignores Research Showing that Closed Formularies Hurt Patients, Lower Adherence, and Do Not Reduce Health Care Costs

Oregon’s Proposed Amendment threatens the health of Medicaid members by limiting access to a host of medicines and imposing significant restrictions in creating a closed formulary. Medicaid members are more likely to be in fair or poor health and have complex and chronic health conditions that often require access to a broad range of medicines compared to those with

⁸⁸ <https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/D-F/FINAL-CARES-Awardees-Overview-Rev.pdf>.

⁸⁹ PhRMA Covid-19 Collaborative Actions to Reach Equity (CAREs) Grant: Spurring Ideas for a More Equitable Future Available at: https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/COVID-19_Community_Action_Health_Equity_Grant_RFP.pdf.

private insurance.⁹⁰ If Oregon chooses to adopt the Proposed Amendment, OHP members will have no other options if the formulary does not include a needed medication. The direct damage from a closed formulary is easy to anticipate—and highly concerning—in view of the extensive research documenting the consequences of restricting access to prescription drugs. Importantly, these studies show that access restrictions reduce adherence to prescribed medication regimens, worsen health outcomes, and drive up long-run costs, both to Medicaid and other state and local programs.

Oregon's proposal to restrict access to one drug per class would ration care and deny members access to a diverse range of treatment options that would best suit their health, biology, and preferences. Research has found that allowing patients and doctors a choice of medicines can increase efficacy of treatments, lower incidence of adverse events, and lower the chances of drug interactions.^{91,92,93}

We offer here a small sampling of the many studies that underscore the important role that a *choice* of medicines plays in improving patient outcomes. Without access to multiple drugs in a class, including the latest formulations, physicians are hindered in their ability to effectively treat or manage patients' medical conditions.

- A *New England Journal of Medicine* study found that patients who had capped benefits were more likely to have higher blood pressure and cholesterol levels compared to those without capped benefits.⁹⁴
- For patients with depression, many studies have shown that a substantial number of patients who fail to respond to first-line selective serotonin reuptake inhibitors will achieve a clinically meaningful response when switched to another drug in the same class.^{95,96,97}
- New formulations of HIV medicines that combine up to four medicines with different mechanisms have increased adherence and worked to avoid drug resistance, further reducing additional health care costs.^{98,99,100}

⁹⁰ MACStats: Medicaid and CHIP Data Book, MACPAC (December 2019), <https://www.macpac.gov/wp-content/uploads/2015/12/MACStats-Medicaid-and-CHIP-Data-Book-December-2019.pdf>.

⁹¹ Joseph A. DiMasi & Laura B. Faden, Competitiveness in Follow-On Drug R&D: A Race or Imitation?, 10 NATURE REVIEWS DRUG DISCOVERY 23 (2011).

⁹² Richard M. Turner et al., Parsing Interindividual Drug Variability: An Emerging Role for Systems Pharmacology, 7 WILEY INTERDISCIPLINARY REVIEWS: SYSTEMS BIO. & MED. 221 (2015).

⁹³ C. Daniel Mullins et al., Persistence, Switching, and Discontinuation Rates Among Patients Receiving Sertraline, Paroxetine, and Citalopram, 25 PHARMACOTHERAPY 660 (2005).

⁹⁴ John Hsu et al., Unintended Consequences of Caps on Medicare Drug Benefits, 354 NEW ENG. J. MED. 2349 (2006).

⁹⁵ Michael E. Thase et al., Citalopram Treatment of Fluoxetine Nonresponders, 62 J. CLINICAL PSYCHIATRY 683 (2001).

⁹⁶ Michael Bauer & Andreas Baumgartner, Fluoxetine-Induced Akathisia Does not Reappear After Switch to Paroxetine, 57 J. CLINICAL PSYCHIATRY (1997).

⁹⁷ C. Daniel Mullins et al., Persistence, Switching, and Discontinuation Rates Among Patients Receiving Sertraline, Paroxetine, and Citalopram, 25 PHARMACOTHERAPY 660 (2005).

⁹⁸ Jeannette R. Ickovics et al., Consequences and Determinants of Adherence to Antiretroviral Medication: Results from Adult AIDS Clinical Trials Group Protocol 370, 7 ANTIVIRAL THERAPY 185 (2002).

⁹⁹ David R. Bangsberg et al., A Single Tablet Regimen Is Associated with Higher Adherence and Viral Suppression than Multiple Tablet Regimens in HIV+ Homeless and Marginally Housed People, 24 AIDS 2835 (2010).

¹⁰⁰ Jean B. Nachega et al., Lower Pill Burden and Once-Daily Antiretroviral Treatment Regimens for HIV Infection: A Meta-Analysis of Randomized Controlled Trials, 58 CLINICAL INFECTIOUS DISEASES 1297 (2014).

- A systematic literature review of nearly 100 studies concluded that “formulary restrictions were most frequently negatively correlated” with desirable outcomes, including a consistent negative effect on medication adherence.¹⁰¹ Medication non-adherence can have serious health consequences, and may cost the U.S. economy up to \$300 billion annually in “avoidable” health care expenditures, as discussed in a 2017 *New England Journal of Medicine* article.¹⁰²
- A closed formulary involves “one size fits all” determinations about clinical efficacy and cost-effectiveness, determinations that inevitably fail to accommodate the diverse needs of a heterogeneous patient population like Oregon’s Medicaid population, which includes pregnant women, people with significant disabilities, and parents who face only acute or mild-to-moderate chronic health conditions. A recent study found that, if the Oregon Medicaid program implemented rigid cost-effectiveness criteria for a set of chronic conditions treated with long-term drug regimens, up to 100% of affected members would need to change their current prescriptions.^{103,104}
- The evidence shows “a clinical and economic advantage to utilizing newer versus older drugs.” However, drug access restriction programs have been shown to drive “an increase in the age of drugs prescribed for Medicaid beneficiaries versus non-Medicaid patients.”¹⁰⁵ By further limiting coverage for the newest, most innovative medicines under a closed formulary, Oregon would be telling its most vulnerable citizens that they don’t deserve full access to cutting-edge therapies.
- For curative hepatitis C antivirals, a 2016 study concluded that Medicaid policies allowing only certain members to access those drugs were “*more costly and less effective than unrestricted, full-access strategies.*”¹⁰⁶
- A study published in *The American Journal of Public Health* found that formulary restrictions for Medicaid members in Arizona living with rheumatoid arthritis had unintended consequences including increasing hospitalizations by 50% and costing an additional \$900 per patient annually.¹⁰⁷

¹⁰¹ 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 PHARM. 677 (2014).

¹⁰² Zullig, LL, Bosworth, H, Engaging Patients to Optimize Medication Adherence, 3 NEJM CATALYST (2017).

¹⁰³ Impact Analysis of ICER Formulary Implementation in Medicaid, XCENDA, https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/icer-medicaid-analysis_march-2019.pdf?la=en&hash=03590A12822FB95144692F0BF6FFF846E2E26F1A (last visited Dec. 12, 2021).

¹⁰⁴ Applying Icer Assessments In Oregon Could Limit Patients’ Access To Medicines, XCENDA, <https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/Applying-ICER-Assessments-Oregon-Fact-Sheet.pdf> (last visited Dec. 15, 2021). The conditions studied were: multiple sclerosis (100% of prescriptions would need to be changed), rheumatoid arthritis (84%), non-small cell lung cancer (42%), and asthma (52%).

¹⁰⁵ Frank R. Lichtenberg, The Effect of Access Restrictions on the Vintage of Drugs used by Medicaid Enrollees, AM. J. MANAGED CARE (2005).

¹⁰⁶ Alexis P. Chidi et al., Economic and Public Health Impacts of Policies Restricting Access to Hepatitis C Treatment for Medicaid Patients, 19 VALUE HEALTH 326-34 (2016) (emphasis added).

¹⁰⁷ Tricia J. Johnson & Stephanie Stahl-Moncada, Medicaid Prescription Formulary restrictions and Arthritis Treatment Costs, 98 AM. J. PUBLIC HEALTH 1300 (2008).

- A 2015 review conducted by the University of Southern California noted the following research findings regarding Medicaid access restrictions on psychiatric drugs:¹⁰⁸
 - Medicaid formulary restrictions for members with severe mental illness result in few drug cost savings, worse member outcomes, higher overall Medicaid spending, and increased incarceration rates.
 - Restricting access to antidepressants drove a 17% increase in the likelihood of hospitalization for a mental health condition; as a result, there was no evidence of overall Medicaid savings from the access restriction.
 - Restricting access to schizophrenia and bipolar medicines increased inpatient and total costs to the Medicaid program by 10 to 23%, without lowering pharmacy costs.

As these findings demonstrate, closed formularies inhibit individualized patient care by limiting access to the specific drug—or combination of drugs—that will most effectively treat or manage the patient’s conditions.

Section 1115 is intended to foster state experimentation by allowing for “experimental, pilot, or demonstration projects.” In light of the robust evidence base summarized above, there is nothing for Oregon to “test” or learn by developing a closed formulary: the literature is rife with examples of the negative consequences that flow from restrictions on member access to prescription drugs. As the Ninth Circuit Court of Appeals explained more than 25 years ago, a Section 1115 project must have a “research or a demonstration value”; a “simple benefits cut, which might save money, but has no research or experimental goal, would not satisfy this requirement.”¹⁰⁹

In this case, Oregon’s proposed “benefits cut” may actually *increase* total Oregon health care spending, given the evidence that limiting members’ access to needed drugs will lead to worse health outcomes and, therefore, greater utilization of other health care services, such as emergency visits and hospitalizations. As it is, Section 1927 affords states ample opportunities to impose appropriate safeguards around prescription drug utilization, as set forth in section II of this letter.

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We understand that states face a considerable challenge in ensuring residents have access to quality, affordable health care, and recognize Oregon’s desire for flexibility and the imperative to reduce costs throughout OHP. PhRMA remains committed to helping Medicaid members access needed medicines so that every member, in consultation with their physician, has access to therapies that can improve their quality of life. The Proposed Amendment’s closed formulary approach represents a step backwards in pursuit of that goal. This policy definitively fails to promote the objectives of the Medicaid program, as demonstrated by the robust literature

¹⁰⁸ Dana Goldman & Seth Seabury, Medicaid Access Restrictions on Psychiatric Drugs: Penny-wise or Pound-Foolish?, USC SCHAEFFER (February 1, 2015), <https://healthpolicy.usc.edu/research/medicaid-access-restrictions-on-psychiatric-drugs-penny-wise-or-pound-foolish/>.

¹⁰⁹ *Beno v. Shalala*, 30 F.3d 1057, 1069 (9th Cir. 1994).

demonstrating the negative effects of restrictions on prescription drug access. Closed formularies constrain physician discretion, undermine patient-centered care, and heap additional administrative burdens on patients and providers. The ultimate result is lower medication adherence, worse patient health outcomes, widened health disparities, and higher overall costs for the Medicaid program.

As Congress and HHS continue to work with states to achieve these goals, the basic compromise of Section 1927 must remain in place, as it serves the dual goals of cost-control and access to treatment in the Medicaid program. Unwinding this statutory bargain is not permitted by the law and would undercut the quality of patient care and is unnecessary in light of the significant flexibility states have under existing law. Medicaid costs and broader state fiscal issues need to be addressed holistically. For these reasons, we strongly urge Oregon to withdraw its Proposed Amendment from the Application.

Thank you for the opportunity to comment on this important matter. We welcome the opportunity to continue this conversation with the state. Please contact Joanne Chan at jchan@phrma.org or Dharia McGrew at dmcgrew@phrma.org if you have any questions related to this issue.

Sincerely,



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