

CareOregon Comments on Oregon's 2022-2027 1115 Waiver Draft Application

For over 25 years CareOregon has served Oregon Health Plan members and currently manages benefits for over 500,000 Oregonians through ownership of Columbia Pacific Coordinated Care Organization (CCO) and Jackson Care Connect, our partnership within Health Share of Oregon, and tribal care coordination. Together, we deeply share the Oregon Health Authority's commitment to erasing health disparities by 2030 and appreciate the direction in which the draft application and waiver concepts take us to achieve that goal.

It is in this context that we still have remaining questions regarding the health equity investment strategy and the implementation of Community Investment Collaboratives. We support the intention behind these concepts because of the deep connection we have developed over ten years of implementing the coordinated care model within the Portland Metro area, the North Coast, and Southern Oregon. This work has allowed us to successfully forge partnerships and gain understanding of our communities' needs, while learning how best to work collaboratively to meet these needs. Furthermore, critical structures strengthening the feedback loop between CCOs and the communities we serve, such as, Consumer Advisory Councils (CACs), Comprehensive Behavioral Health Plans (CBHPs), and Community Health Improvement Plans (CHPs), are built into the foundation of the CCO model and continue to be advanced by the CCO 2.0 contract. Our primary questions regarding the health equity investment strategy continue to be: 1) how to prevent the potential for siloed and parallel investments in community infrastructure; 2) how CICs will be integrated into the existing community-based contractual components of the CCO model; and 3) what will accountability for outcomes look like given 1% of CCO budgets will be directed towards CICs for infrastructure?

With a commitment to addressing health equity head-on, we believe that progress can be made by building on our existing transformation successes. To achieve this, we look forward to continued dialogue on how to best implement the final approved waiver, leveraging our successes while continually improving how we meaningfully collaborate with the communities we serve on health equity investments.

Regarding changes to the global budget, we support OHA's strategy of moving the coordinated care model to a global budget that is more stable and sustainable. A predictable budget forecast, that remains flexible to account for unexpected budget trends or population changes, will help CCOs better plan operations while aligning activity with cost control. A global budget will also alleviate the administrative burden that accompanies annual rate development. While overall supportive of the larger concept, we do caution the removal of the requirement for actuarially sound rates, a longstanding mechanism to protect CCOs from insolvency. We believe actuarially sound rates are necessary to have a financially stable system for the long term.

As stewards of public funds, we appreciate the innovation and inclusion of strategies to help the system address rising pharmacy costs through adoption of an evidence-based commercial-style formulary. We believe the following changes (underlined) help make clear our goal of supporting CCO members' access to FDA accelerated pathway approved pharmaceuticals that demonstrate clinical effectiveness within existing FDA timeframes:

Changes to Prescription Drug Benefits

Ability to define a preferred drug list for pharmacy benefits

Oregon seeks the ability to more closely manage pharmacy costs in its Medicaid program, through a two-part strategy:

A. Adopt a commercial-style limited formulary approach

Taking a limited formulary approach for adult members, including at least a single drug with standard FDA approval per therapeutic class, would enable OHA and CCOs to negotiate more favorable rebate agreements with pharmaceutical manufacturer partners. Oregon would keep an open formulary for children. For each therapeutic class, manufacturers could be offered an essentially guaranteed volume in exchange for a larger rebate. Currently, OHA and CCOs have limited ability to explore and enact such agreements with manufacturers, given the requirement to cover all drugs in the Medicaid rebate program. OHA would create a collaborative process that includes CCOs to select drugs for the closed formulary.

In recent years, the majority of commercial pharmacy benefit managers (PBMs) have adopted such closed formularies, which allow them to customize their drug offerings based on clinical efficacy and cost considerations. As an example, for 2021 CVS Health excluded from its formulary 57 additional products—some because a less expensive, medically equivalent drug had become available and some because the drugs were hyperinflationary, having dramatically increased in price without clear justification. Medicare Part D commercial plans are also permitted to employ such closed formularies (as authorized under 42 CFR 423.120) with at least two drugs per therapeutic class. Medicare Part D plans may also include just a single drug per class if only one drug is available, or if only two drugs are available, but one drug is clinically superior. Given that Medicare and other commercial plans are permitted to adopt closed formularies, we believe Oregon should have the same flexibility for Medicaid. As such, we request a formulary that is driven by clinical evidence and lowest net cost to best serve Oregon Health Plan members.

B. Allow exclusion of drugs with limited or inadequate evidence of clinical efficacy

Many drugs coming to market through the FDA's accelerated approval pathway have not yet demonstrated clinical benefit and have been studied in clinical trials using only surrogate endpoints. Oregon seeks the ability to use its own rigorous review process to determine coverage for drugs previously granted accelerated approval, but that have not confirmed benefit with conversion to full FDA approval in the expected time interval. Through this process, the state could incentivize drug sponsors to complete their regulatory obligations to demonstrate clinical benefit as laid out by the FDA upon approval. This will allow Oregon to avoid exorbitant spending on high-cost drugs marketed to treat conditions that have yet to demonstrate a clinical benefit despite ample time to do so. Many stakeholders agree that national policy changes are necessary to ensure proper oversight after approval of accelerated pathway drugs based on surrogate endpoints. Current rules do not allow Medicaid programs to exercise discretion about whether these drugs should be covered without being fully clinically proven and despite drug manufacturers not meeting obligations set forth as a condition of accelerated approval.

To that end, Oregon proposes to build on the success of the Prioritized List of Services and limit the coverage of drugs approved through the accelerated pathway without traditional approval. Under this proposal, Oregon would utilize the timelines set out in the FDA approval letter and review confirmation

of benefit data in peer reviewed literature or clinicaltrials.gov. Applying the FDA developed guidance and timetables ensures a universal standard, clinically feasibility, and drug sponsor agreement.

New drugs approved under the FDA's accelerated approval pathway tend to be specialty medications that represent a significant portion of pharmacy expenditures. As such, it is our responsibility to ensure we are following through with the promise of expedited approval pathways. In addition, re-formulations of older, existing drugs that provide no incremental clinical benefit might be labeled non-formulary as well. While commercial payers can exercise discretion to exclude drugs from their formularies in certain situations, OHA and CCOs currently do not have this ability.

CareOregon appreciates the Oregon Health Authority's partnership in serving our Oregon Health Plan members through its commitment to advancing our state's unique coordinated care model. We are particularly supportive of all efforts to expand Continuous Eligibility for those eligible for OHP, as we know that this will add stability and improve the continuity of care for the population that we serve. Given the many details yet to be determined as implementation of the final approved waiver takes shape, we look forward to continuous engagement in the 1115 waiver process as we partner in achieving an equity-centered system of health.

Sincerely,

A handwritten signature in black ink, appearing to read 'Stefan Shearer', written in a cursive style.

Stefan Shearer, MPA:HA
Public Policy & Regulatory Affairs Specialist
CareOregon