In response to the Oregon Health Authority's draft application for the next §1115 Medicaid Demonstration Waiver

The §1115 Medicaid Demonstration Waiver offers an opportunity to innovate, improve, and strengthen the care members of the Oregon Health Plan (OHP) receive across the delivery system and coordinated care model. For these reasons, we focused our collective efforts on the principles below throughout the waiver application development process over the past year.

CCO OREGON FRAMING FOR THE §1115 MEDICAID DEMONSTRATION WAIVER RENEWAL

1. Continue progress towards a true global budget that is flexible and allows for community-defined infrastructure development with improved health and social outcomes while maintaining a 3.4% rate of growth for CCOs.
2. Diminish regulatory barriers to delivery and payment innovation and maximize health system cost savings and federal investments in health and social services.
3. Further Oregon's health transformation goals, including new payment models, expanded coverage access, eliminating health disparities, and the quadruple aim.
4. Increase local accountability ensuring program goals and implementation are community-based, optimize existing systems, and center the elimination of health disparities.
5. Strengthen the coordinated care model, support the goals of CCO 2.0, and set a stage for growth towards CCO 3.0.

These principles were included in our May 2021 public comment to the Oregon Health Policy Board (OHPB). This comment also recommended additions to the Oregon Health Authority's (OHA's) initial ideas for the §1115 Medicaid Demonstration Waiver renewal. We offered further public comment in July 2021 to the OHPB after OHA posted the first draft of the waiver renewal concept papers. In review of the OHA's revised concept papers released in early November 2021 and the draft waiver renewal application posted on December 1, 2021, we appreciate the incorporation of many of our earlier suggestions; these include developing care coordination or targeted coverage for those OHP members that are justice-involved including the pre-adjudication phase or placed at the Oregon State Hospital or Oregon Youth Authority as well as improved access to peer support with less barriers, such as the federal treatment plan requirements.

Moreover, we appreciate the overall direction of the draft application and proposed waiver concepts. We agree that maintaining and/or expanding coverage or care coordination for targeted populations and specifically those facing transitions where they may currently lose their continuity of care, supports, or coverage should be a priority. For these concepts to succeed, there are system challenges outside of the §1115 Medicaid Demonstration Waiver

that must be considered, such as a plan to fund the state's portion of the expansions and new programs in the short and long terms. Looking to the Triple Aim, we must ensure sustained funding and thereby program continuity to improve member experience and overall population health while maintaining a reasonable rate of cost growth.

The concepts in the §1115 Medicaid Demonstration Waiver renewal and other proposed expansions in coverage and care will impact our workforce at a time when we are already experiencing devastating burnout, retention, and recruitment challenges across the delivery system. We call upon the state to launch a coordinated effort with stakeholder input from all regions of Oregon to address the workforce crisis across all provider types and settings. We realize this may not be in the actual waiver application but request a statewide, streamlined public forum to begin now so Oregon may prepare for the implementation of the waiver concepts and other programs that will increase or expand access to care and coverage.

Similarly, expansions in care and coverage will be most successful with improved infrastructure elements, such as Health and Community Information Exchanges. Connect Oregon and similar platforms, which CCOs and community-based organizations have been developing in partnership for years, are critical in urban and rural communities as we continue to transform the delivery of care to ensure referrals, warm handoffs, a quality member experience, and making the best use of the already stretched health and social service workforce. We believe this work is critical to guarantee that the proposed coverage expansions lead to the delivery of successful and sustainable whole person quality care and will engage with the Health Information Technology Oversight Committee's work over the next year(s) to scale this work across Oregon.

As our previous comments from May 2021 and July 2021 reflect, we support the intentions behind the proposed health equity investment strategies and have questions about how they will be operationalized, align with existing processes and contract expectations, and include accountability for outcomes and optimized spending. CCOs and coordinated care partners are committed to working with historically underserved populations to better identify systemic health disparities and leverage the coordinated care model to amplify the community role in financial decision-making. We acknowledge that the voices of those with lived experience are essential to guiding our work. We understand that we must center the perspectives of those impacted by institutionalized racism, colonialism, sexism, ableism, and heteronormativity to ensure we eradicate all remnants of such perspectives in our health delivery system from frontline workers to system partners and from the state agency to our federal partners. We know these conversations may be challenging and that they are necessary.

Our goal is to better integrate our work with local communities as opposed to work apart from it. Regional networks and partnerships developed across the coordinated care model leverage

the role of the CCO as the hub or convener with a focus on local decision making and accountability. With CCOs as the hub, provider, community-based partners, and OHP member voices are engaged in identifying and choosing regionally developed strategies to improve overall health and address disparities through the CCO Community Advisory Councils (CACs), Boards, and the development of systems and strategies, such as the Community Health Improvement Plans (CHPs), Health Equity Plans (HEPs), and Comprehensive Behavioral Health Plans (CBHPs).

OHA's draft §1115 Medicaid Demonstration Waiver application identifies two primary sources of funding for the health equity investment strategy; these investments include 1% from CCO budgets. Questions remain about which entities(y) will be accountable for the outcomes of these funds, including how they may be reflected in various CCO deliverables and metrics and how the 1% would be calculated. Further, many details are yet to be defined to ensure the proposed health equity investment strategy is integrated with the existing coordinated care model and contracting expectations (i.e., the CHP, HEP, and CBHP) to avoid duplication at the patient, provider, and payer level and prevent the creation of new funding or programmatic silos. We also need to understand how the voice and work of the CACs and other existing community-based committees will be integrated. Moreover, it is important that OHA partner with other state agencies, such as those administering housing, education, and criminal justice, to maximize all opportunities for funding and the elimination of barriers to care, services, and supports.

Lastly, we appreciate the inclusion of strategies to address the impact of pharmacy costs on Medicaid spending in Oregon. Below are suggested adjustments (in blue) to the pharmacy strategies as presented on pages 76 and 77 of OHA's draft application. Our goal is to support the FDA's accelerated pathway for innovative drugs and ensure these drugs move to full evidence-based FDA approval on the expected timeline.

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 evidence-based formulary approach

Taking an evidence-based, 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 evidence-based formulary.

In recent years, the majority of commercial pharmacy benefit managers (PBMs) have adopted such limited 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 evidence-based, limited 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 evidence-based, limited 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 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.

In closing, the sustained success of many of the proposed concepts in the draft §1115 Medicaid Demonstration Waiver application will rest in implementation and operational specifics. We know many of these elements are yet to be determined and understand that the submission of the application is the start of the process. We look forward to partnering with the OHA, regional and system partners, providers, and advocates on next steps and those details that will ensure success. We expect organizations represented here may also submit individual comments presenting similar and additional ideas, concerns, or questions. We appreciate your consideration of our comments and look forward to next steps. Thank you for your work.