October 11, 2016

Oregon Pharmacy and Therapeutics Committee
500 Court Street NE
Salem, OR 97301

Delivered via email

Re: Hepatitis C Direct-acting Antivirals (DAA)

Dear Oregon Pharmacy and Therapeutics Committee:

The undersigned coordinated care organizations (CCOs) serve Oregon Health Plan (OHP) members across the state. The membership association, CCO Oregon, of which some of our organizations are members, seated a committee of CCO pharmacy directors to address various CCO pharmacy issues. That committee has developed a position statement on OHP coverage of Hepatitis C (HCV) Direct-acting Antivirals (DAA). We are writing to support the CCO Oregon position (attached).

Traditionally, the benefit package for the OHP is determined by the Health Evidence Review Commission's (HERC) prioritized list and recommended coverage guidelines. CCOs are required to cover services "above the line" on the prioritized list but can develop community specific coverage guidelines. A recent change to the CCO contract language will require CCO coverage guidelines to meet or exceed the fee-for-service coverage guidelines for prescription drugs, which, as you know, are set by your organization. This means that the decisions you make will have a statewide impact on the OHP.

We understand that the Pharmacy and Therapeutics Committee is considering an expansion of coverage of HCV DAAs to people with Stage F2 liver fibrosis and below. The Oregon Health Authority has estimated this expansion to cost an additional $45 million in state general fund dollars and $260 million overall. We agree that CCOs are obligated to treat HCV-infected individuals who are experiencing illness, and we have worked with hepatologists in our communities to develop effective and sustainable coverage guidelines that are aligned with the FFS program's current guidelines. We hope that you will consider the impact of this proposed coverage expansion on CCOs' ability to serve the health care needs of the entire OHP population. Without substantial funding increases to offset the additional cost of this coverage mandate, CCOs risk the need to cut other necessary programs and services.

We ask that you consider the totality of the CCO Oregon Pharmacy Committee's analysis and the potential impact of this coverage guideline on the OHP as a whole.

Sincerely,

Cascade Health Alliance
Eastern Oregon CCO
FamilyCare Health
Health Share of Oregon
Intercommunity Health Network CCO
PacificSource Community Solutions
Trillium Community Health Plans
Western Oregon Advanced Health
Willamette Valley Community Health
Coalition for a Healthy Oregon

Oregon Pharmacy and Therapeutics Committee
September 29, 2016

Public Comment
Re: Hepatitis C Direct-acting Antivirals (DAA)

CCO Oregon is an independent non-profit member association that aims to be shaped by and to serve all stakeholders that touch coordinated care in Oregon. Our purpose is to support the delivery of exceptional care at reduced costs while promoting the health and well-being of Oregonians. This is primarily accomplished through a variety of workgroups focused on a topic related to coordinated care.

The Pharmacy & Therapeutics Committee's mission is "To evaluate available evidence-based research using a transparent process to encourage safe, effective, and financially sustainable drug use policies that maximize access to high value medications for patients served by the Oregon Health Plan and other health care programs under the Oregon Health Authority." The recommendations of this group have the potential to impact local CCOs and we thank the committee for the opportunity to provide comment today.

Safe:

Patient safety is an important consideration with any new medication. Since the clinical trial population excludes several comorbid conditions, there is limited safety data in HCV-infected individuals with many chronic diseases and history of substance use. The US Food and Drug Administration notice dated October 22, 2015 is an example, which requires the manufacturer of Viekira Pak and Technivie to include information about serious liver injury adverse events. There is also limited drug-drug interaction data, which may cause harm or impact the effectiveness of the therapy. This was seen with addition of amiodarone as a potentially dangerous drug-drug interaction after the approval of Sovaldi. There is potential for other discoveries with newer agents that will be used to treat HCV and as the populations treated with these novel drugs expands beyond that of the study populations.

Effective:

Our primary objective, in treating HCV-infected individuals, is effective sustained virological response (SVR) at 12 and 24 weeks post therapy with low incidence of adverse events, treatment failure, and reinfection. We are concerned that there is limited data available regarding SVR for patient populations that were excluded from clinical studies.

Additional considerations to enhance effectiveness include an adequate provider network and robust case management programs designed to follow HCV patients longitudinally throughout their course of care to monitor, measure, and support patients while mitigating potential treatment

failure due to co-morbid diseases using a biopsychosocial approach. Providing holistic and coordinated care will help CCOs to meet the objective of a high SVR.

Financially Sustainable:

CCO Oregon supports the treatment of HCV-infected individuals, however, there needs to be adequate resources, funding, and workforce to address the needs of our entire population. We recommend that DAA therapy be prioritized for patients with advanced cirrhosis and fibrosis or in those with extrahepatic manifestations. If a CCO is to treat additional patients, this may not be sustainable if the sum of taking care of the HCV obligations and all the other health care obligations is not adequately funded which would then mean HCV treatment was being prioritized and take resources away from other services.

We are reminded by the CMS Program Notice date November 5, 2015 titled "Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Drugs" of the common obligations the State of Oregon, the CCOs, and additional key stakeholders share to treat and eradicate Hepatitis C. Before we expand treatment to HCV-infected individuals stage F2 and above, we need to ensure that there is a pathway to a sustainable funding source and robust HCV treatment infrastructure that is able to increase in scale to provide safe, effective therapy while not jeopardizing our larger obligations to meet the healthcare needs of the populations that we serve. Most important, we need to make sure that those at highest risk continue to have access to appropriate therapy.

CCO Oregon believes in the efficacy of the coordinated care model. The rising costs of DAA and other medications are forcing CCOs to allocate additional resources to pharmacy budgets and away from other programs. Anecdotally, for one individual CCO treating the HCV-infected at stage F2 and above patients would require 17% of the global budget. If this continues, CCOs will need to have access to supplemental funds for these emerging medications or have alternatives for paying for these medications.

Oregon CCOs have created remarkable and innovative services for their local communities. We want this work to continue, however, this may not be possible if the CCO budget has a growing pharmacy component taking resources away from other services, therefore, we respectfully request that this committee take into consideration when providing recommendations to the Oregon Health Authority the impact the decisions have on local CCOs in providing services to their communities, and without sustainable funding mechanisms for high cost medications, many services may have to be de-funded.

Thank you for the opportunity to provide comment today.

Sincerely,

CCO Oregon