



Caring Ambassadors Program
Lorren Sandt, Executive Director
P.O. Box 1748
Oregon City, OR 97045

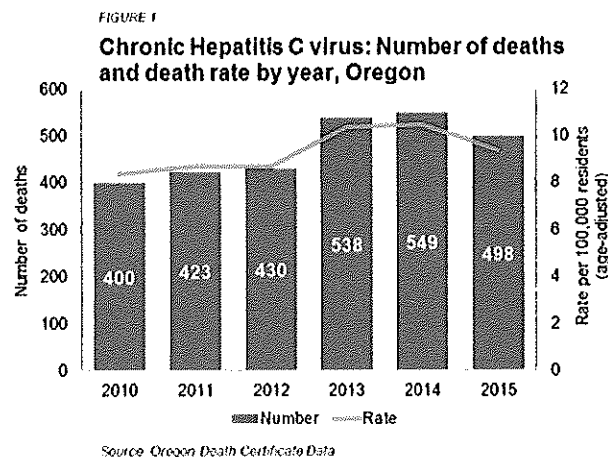
Public Comment
HCV Antivirals Class Update and Treatment Guidelines

OSU Drug Use Research and Management Program
Oregon Drug Use Review / Pharmacy & Therapeutics Committee
September 28, 2017

The Caring Ambassadors Program is a national, nonprofit, advocacy organization based in Oregon City, Oregon. We respectfully submit our written comment on the current criteria and suggested update to the current Hepatitis C PDL class for treatment of Chronic Hepatitis C Virus (HCV). **We ask that Oregon's Medicaid program allow full access to all FDA approved hepatitis C direct acting agents by placing all these medications on the Preferred Drug List (PDL). This will allow medical decisions to be made between provider and patient, and will remove the current restrictions in place limiting patient access to these medications in accordance with the Center for Medicaid and CHIP Services' November 5, 2015 guidance sent to all state Medicaid programs.**

1 year ago, and 1 year Nine months ago, I testified on this same issue and nothing has been changed accept, the state has been sued so you must respond, many more Oregonians have been refused treatment, and many have died.

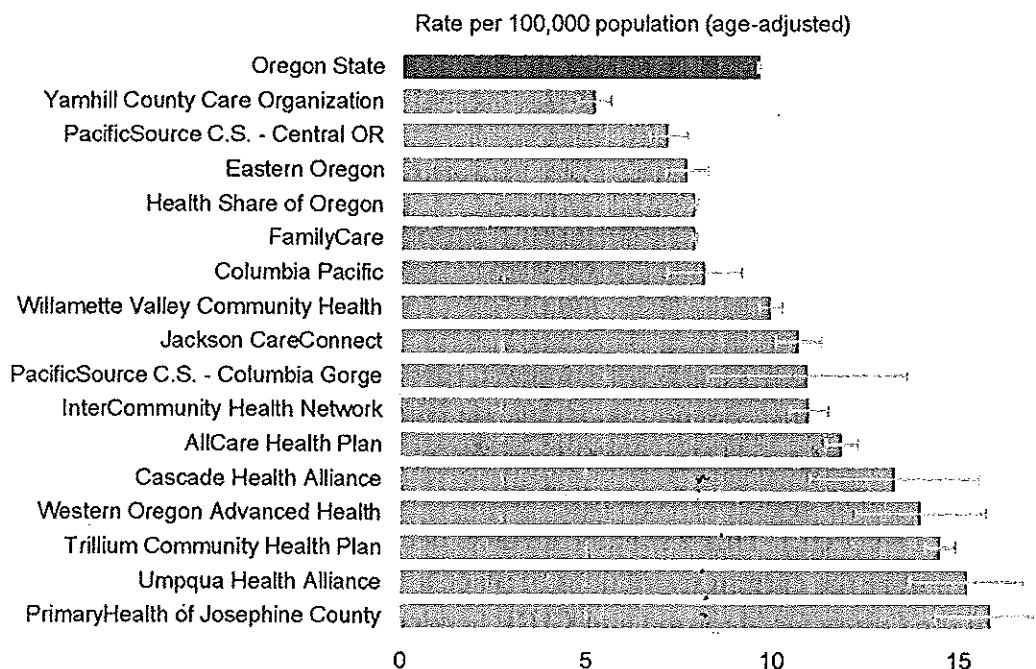
In Oregon, deaths from chronic HCV have risen over the past 10 years, and the annual number of deaths has hovered around 500 in each of the last three years (2013-2015; Figure 1).



Source: Oregon State Population Health Indicators

Chronic Hepatitis C mortality in regions covered by Coordinated Care Organizations, 2011–2015

Gray lines represent confidence intervals



Your Zip Code Matters

Mortality from HCV does depend on access to the cure. The areas where we receive the most complaints from consumers about treatment access align with the CCO regions of coverage and highest mortality. The OHA values speak about health equality across the state. Clearly that is not happening in HCV. Are the CCO's actively screening for HCV to identify the undiagnosed or are they just handling the known cases?

Remove Substance Use Restrictions

The HCV/Opioid syndemic we are facing requires us to face the science and treat all people with hepatitis C regardless of ongoing drug use. A recent study of 103 people that started treatment, 99 completed treatment, and 96% were cured. [Grebely, EASL 2017] People who use drugs should be a priority so we can eliminate the community viral load and reduce future transmission. Your own research revealed no data to support a specific minimum length of abstinence from illicit substances or alcohol before treatment, nor are they less likely to be cured. Yet the current guideline calls for them to be enrolled in a treatment program under the care of an addiction specialist — there is no substantiated reason for this exclusion and adopting it bars many of the patients most in need of treatment from being cured of their virus. This exclusion is not in line with the guidelines of AASLD. The State of Oregon is currently guilty of discriminating against its own most marginalized citizens.

Access to Fibroscan

The PA criteria on Fibroscan should be revisited as there is only 1 machine in the state of Oregon.

The Cochrane Review

The Cochrane Group Review concluding that there is a lack of valid evidence supporting the benefit of direct acting antiviral (DAA) therapy for chronic infection with hepatitis C virus (HCV), and its supposition: “the possibility of potentially harming people with chronic hepatitis ought to be considered before treating people with hepatitis C with DAAs.” is a misleading and a harmful conclusion.

The Review’s conclusion stating a lack of evidence that SVR impacts long term clinical outcomes (morbidity) and mortality ignores both fundamental mechanisms and mounting published literature supporting the clear clinical benefit of SVR obtained with DAAs.

With new cost saving treatments now available we have a chance to halt this disease in its tracks; but not if we continue to discriminate against people accessing the Oregon Health Plan. **We are requesting that you remove the current access restrictions and allow doctors and their patients to decide the right course of therapy so that the Oregon Health Plan will be in accordance with the CMS guidance, and all Oregon Medicaid beneficiaries with hepatitis C can gain access to the hepatitis C cure medications in a timely fashion.** Denying treatment to Oregonians who can be cured of their virus and creating a new population of patients is both a costly and a deadly path for all concerned.

Thank you for your time and consideration.



Lorren Sandt
Executive Director
Caring Ambassadors Program