Hepatitis C Drugs: A Look at Emerging "Netflix" Payment Models and Patient-Centered Outcomes Research

Wednesday, May 15, 2019
3-4pm Eastern

For Audio, please listen through your computer speakers or call:
(888)378-4398, conference ID#: **993604**

This webinar is supported by the Patient-Centered Outcomes Research Institute.

Welcome and Introductions **Jennifer Reck,** MA, Project Director, National Academy for State Health Policy	
Pete Croughan, Policy Advisor, Louisiana Department of Public Health	
Donna Sullivan, MS, PharmD, Chief Pharmacy Officer, Washington Health Care Authority	
Robyn Liu, MD, MPH, Associate Professor of Family Medicine, School of Medicine, Oregon Health & Science University	
Questions and Discussion	

NASHP Webinar:
How States Pay for Hep C Drugs Using a "Netflix-style" Subscription Model

MAY 15, 2019

Pete Croughan
Policy Advisor,
Louisiana Department of Health

4

Overview

Background on Hep C

- Tied to opioid epidemic
- Growing public health and fiscal crisis

The Louisiana Subscription Model

- "Netflix," structure, amount
- Best price challenge, outcome
- Public Health Elimination Strategy

Note: given current contract negotiations, this webinar will only cover existing publicly available content. More details will be made available following execution of the final contract (summer 2019)

5


We have a cure for hepatitis C. But the neediest can't afford it. Louisiana wants to change that.

Updated by Joshua Sharfstein, Jay Lee, and Rena Conti | Sep 27, 2017, 11:20am EDT

TWEET SHARE

Louisiana Health Secretary Dr. Rebekah Gee listens to questions during a state House floor debate in May 2016. | Kevin Litten, NOLA.com | The Times-Picayune

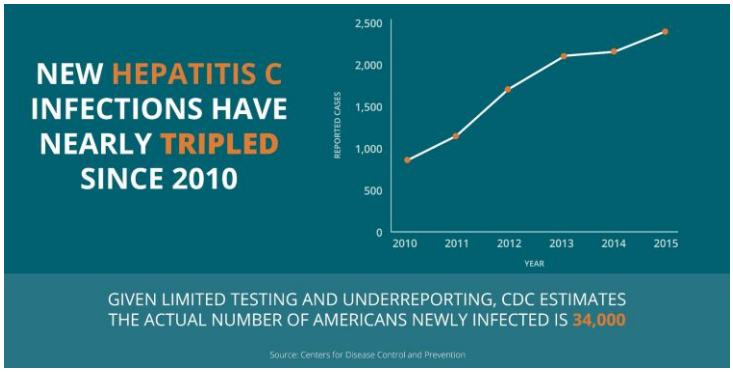
Most Read

The latest White House leaks show Trump's art of the tantrum

"The bottom line for me is my patients are developing organ damage and I have to wait until they have organ damage until I can access medication for hepatitis C."

-Dr. Jason Halperin, an infectious disease clinician in New Orleans

More info: Rebekah Gee, "Louisiana's Journey Toward Eliminating Hepatitis C," Health Affairs Blog, April 1, 2019. DOI: 10.1377/hblog20190327.603623:



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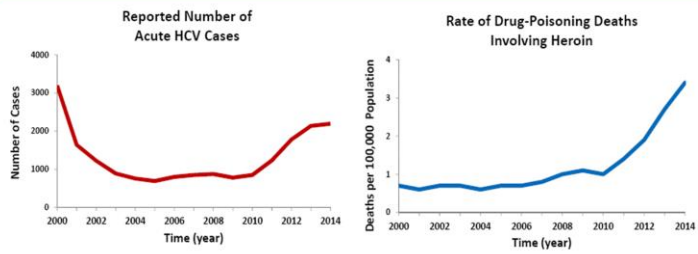
US Trends for Acute HCV Cases (2000–2014) And Heroin-Related Deaths



People who inject drugs (PWIDs) account for ≈ 75% of new HCV infections

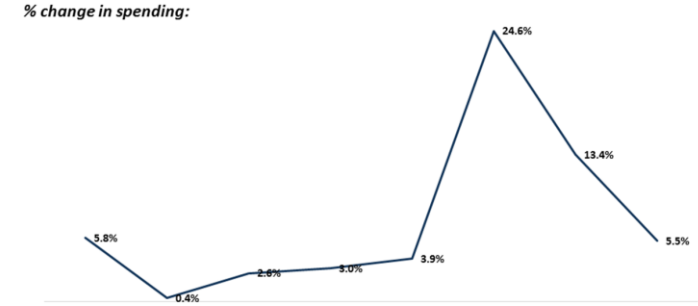
NCHS. National Vital Statistics System: Mortality. www.cdc.gov/nchs. Accessed 6/29/17; CDC. Surveillance for Viral Hepatitis – US, 2014. www.cdc.gov. Accessed 6/29/17.

7

Figure 1

Annual Growth in Medicaid Spending on Prescription Drugs, 2008-2016

% change in spending:



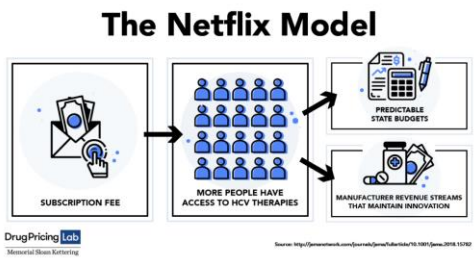
	2009	2010	2011	2012	2013	2014	2015	2016
Total Medicaid Rx Spending:	$20.3B	$20.4B	$21.0B	$21.6B	$22.4B	$28.0B	$31.7B	$33.4B

Source: CMS National Health Expenditure Accounts, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html.

THE HENRY J. KAISER FAMILY FOUNDATION

9

Hepatitis C Treatment Subscription Model



- Structure: Louisiana will pay a drug manufacturer for **unlimited access** to treatment for individuals in Louisiana for a set annual cost over a set contractual period
  - Populations included: Medicaid, Corrections
- Amount: Annual payment to the manufacturer would be **equal to or less than** what the state is currently spending annually to provide antiviral medications to these populations
  - $30M in Medicaid, $5M in Corrections (pre-rebate)

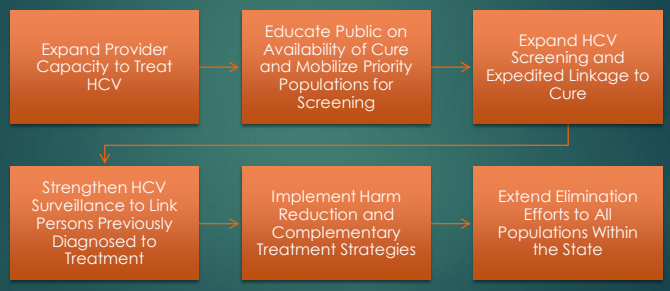
10

Hepatitis C Treatment Subscription Model

- Challenge: Medicaid Drug Rebate Program, "Best price"
- Potential solutions (*from SFO*):
  - **Medicaid**: use of Supplemental Rebates
    - For example, by paying the currently negotiated per-unit price (inclusive of federal rebates only) until the cap has been met, after which the cost of any remaining Medicaid-related DAA purchases would be effectively $0, regardless of volume.
  - **Corrections**: utilizing the 340b Drug Pricing Program
    - For example, utilizing a 340B covered entity providing clinical services to inmates on behalf of the Department of Corrections to purchase DAAs for the Corrections population at a Medicaid Best Price Policy-exempt negotiated price.
- Outcome: "Win-win-win"
  - **Manufacturers:** predictable revenue, gain in market share, good news
  - **State:** predictable expenditures, opportunity to eliminate HCV
  - **Patients:** increased SVR, reduced morbidity, reduced mortality

11

Public Health Elimination Strategy



12

More Information

Resources:

- Louisiana Solicitation for Offers (SFO) (Jan 2019): http://ldh.la.gov/index.cfm/newsroom/detail/5018
- SFO Question and Answer (Feb 2019): http://ldh.la.gov/assets/oph/SFO/SFOWrittenAnswersManufacturers.pdf
- Rebekah Gee, "Louisiana's Journey Toward Eliminating Hepatitis C," Health Affairs Blog, April 1, 2019. DOI: 10.1377/hblog20190327.603623:
- Section 1498 Public Comments and Memo (2017): http://ldh.la.gov/index.cfm/newsroom/detail/4227
- NGA: Public health crises and pharmaceutical interventions: improving access while ensuring fiscal sustainability. https://www.nga.org/wp-content/uploads/2018/08/Public-Health-Crises-and-Pharmaceutical-Interventions.pdf

Thank you:

- Rebekah Gee
- Alex Billioux, Kim Hood, Louisiana Office of Public Health
- Josh Sharfstein, Rena Conti, Jon Gruber
- Peter Bach, Mark Trusheim, Neeraj Sood, Dana Goldman
- AbbVie, Gilead, Merck

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Eliminating Hepatitis C Virus in Washington State

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Washington State Health Care Authority

Our Goal…

…to develop and implement a hepatitis C elimination plan focusing on public health outreach and purchasing

…to significantly reduce this infected population over four years and eliminate much of the burden of hepatitis C from its covered population

Washington State Health Care Authority

Prevalence of Hepatitis C in Washington

- Prevalence of chronic hepatitis C infection in Washington State
  - Approximately 65,000 cases statewide
  - Nearly 40,000 new cases reported from 2012 through 2017
- Estimated infected populations covered through state purchasing
  - Approximately 35,000
    - Department of Corrections (DOC) = approximately 1,900 inmates
    - Medicaid = approximately 24,000 Medicaid enrollees
    - Public Employees (PEBB) = 2,800 members
    - Labor and Industries (LNI) and state hospitals (DSHS) = approximately 100 persons each

Washington State Health Care Authority

Defining HCV "elimination"

A state where HCV is no longer a public health threat and where those few who become infected with HCV learn their status quickly and access curative treatment without delay, preventing the forward spread of the virus.

- WHO has set goal of HCV elimination by 2030:
  - Increase syringe supply coverage from 20 sets per year per PWID at baseline (2015) to 300 sets per year per PWID
  - 90% of those with HCV diagnosed
  - 80% of those eligible treated for HCV by 2030
  - 90% reduction in HCV incidence
  - 65% reduction in HCV mortality

Washington State Health Care Authority

Gov. Inslee's Plan to Eliminate HCV in Washington

- Governor's Directive Released September 29, 2019
- Eliminating hepatitis C requires a two-step approach
  - Comprehensive Public Health Elimination Plan
  - Innovative prescription drug purchasing strategy

Washington State Health Care Authority

Comprehensive Public Health Elimination Plan

- WA Department of Health (DOH) is to create an HCV elimination coordinating committee comprised of public and private partners to develop, by July 2019, a strategy to eliminate the public health threat of HCV in WA by the year 2030
- A Multi-year public health approach to identify people with hepatitis C through outreach, screening, and linkage to care
  - Ensure those living with hepatitis C know their status and are connected to care.
  - Stop the spread of hepatitis C infection through programs like syringe service centers

Washington State Health Care Authority

Innovative Prescription Drug Purchasing Strategy

- Lead a first-in-nation comprehensive procurement of hepatitis C medications purchased by state agencies to get the best prices possible from manufacturers and make sure the treatment is more readily available to all
- Collaborate with other state agencies to leverage market competition and issue an RFP for HCV medications and bona fides services across multiple state purchasers by January 2019
- Engage a multi-state or national organization to develop a strategy to assess the interest and ability to extend the state purchasing and public health strategy to other major purchasers including other states

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Innovative Prescription Drug Purchasing Strategy

- Released an RFP January 24, 2019 to get best possible prices for HCV Treatment for all state purchased health care programs
  - Corrections, Medicaid, Public and School Employees, State Hospitals, Workers Compensation
- Non-Medicaid programs – challenged manufacturers to submit their lowest price
  - PEBB & LNI it works like a rebate
  - DOC and DSHS works through a charge back from the wholesaler
- Gives successful bidder 1st right of refusal for expansion to private purchasers and other states

Washington State Health Care Authority

Innovative Prescription Drug Purchasing Strategy

- Medicaid – Value Based Supplemental Rebate Contract
  - Submitted State Plan amendment for a value based supplemental rebate (SR) contract
  - Modified Subscription model to get a lower guaranteed net unit price to be paid up to the annual maximum for all HCV treatment; then $0.01 per unit there after
- Includes bona fides to support the public health outreach strategy
  - Medical Case Managers - Increased screening and provide for linkage to care
  - Health promotion and education - media campaign promoting HCV prevention, testing, and curative treatment
  - Provider and patient education, increase access to authorized prescribers in rural areas
  - Health Information Exchange Reporting and Analytics

Washington State Health Care Authority

State Partners

Washington State Health Care Authority

Washington State Department of Health

HCA PEB/SEB

Washington Apple Health

Washington State Department of Labor & Industries
Workers' Compensation Services

Department of Corrections
WASHINGTON STATE

Washington State Department of Social & Health Services
Transforming lives

MagellanRx MANAGEMENT

CENTER FOR EVIDENCE-BASED POLICY

State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D)

moda HEALTH

Washington State Health Care Authority

HEPATITIS C: PCORI UPDATE

ROBYN LIU, MD, MPH, FAAFP

MAY 15, 2019

WHERE WE ARE

- HCV History In Brief
  - Discovered in 1989
  - Early treatment difficult, poorly tolerated (interferon, ribavirin)
  - DAAs appeared in 2011
- Eradication takes more than a drug
- PCOR research aiming to fill some gaps:
  - Screening to identify more cases
  - Harms compared to no treatment
  - Direct comparison of treatments in the real world
  - Effectiveness of care delivery models

RAPID-CYCLE RESEARCH: HEPATITIS C (OBSERVATIONAL STUDY)

- 12-month rapid-cycle retrospective observational research study conducted by investigators using PCORnet infrastructure
- Evaluates whether patients with hepatitis C who are prescribed DAAs experience higher rates of adverse events than patients who are untreated
  - hospitalization, acute myocardial infarction, neurological outcomes, acute kidney failure, acute liver failure, hepatic decompensation, multiple organ dysfunction syndrome, liver cancer, and death
- A secondary aim of the study is to evaluate how well the PCORnet Common Data Model characterizes the population with HCV, the severity of disease, medication prescribing and dispensing patterns, and adverse events.
- March 2019

THE PATIENT-REPORTED OUTCOMES PROJECT OF HCV-TARGET (PROP UP TARGET)

- Compares two new all-pill treatments; first head-to-head study of short-term and longer-term outcomes
- HCV-TARGET is the largest international research network and clinical registry of patients undergoing treatment
  - Provides opportunity to evaluate patient-reported outcomes in a diverse spectrum of patients treated in real-world clinical settings.
- Study participants complete surveys to collect information on:
  - Harms that may occur during treatment (side effects, poor functioning, out-of-pocket costs, difficulty with adherence);
  - Benefits of treatment 3 months after it ends (do preexisting HCV symptoms and functioning improve?); and
  - Longer-term toxicities and side effects that may occur up to 1 year after treatment ends.
- Participants will complete surveys at 5 time points: before treatment, twice during treatment, and 3 and 12 months after treatment.
- September 2019

COMPARING ORAL MEDICINES TO TREAT HEPATITIS C VIRUS (HCV) – THE PRIORITIZE STUDY

- Enrolling patients from a network of 45 medical centers with diverse populations
  - Includes African Americans, adults over age 65, people with mental illness, those with multiple medical conditions, and people with a history of drug or alcohol use
- Random assignment to 2 standard of care regimens for HCV genotype 1
  - Sofosbuvir/ledipasvir fixed-dose combination tablet once daily
  - Grazoprevir/elbasvir fixed-dose combination tablet once daily
- Outcome: Absence of HCV at 12 weeks, 24 weeks, and 3 years following treatment
- August 2021

PATIENT-CENTERED HEPATITIS C VIRUS CARE FOR PEOPLE WHO INJECT DRUGS – THE HERO STUDY

- Compares two delivery models for people with Hep C who inject drugs:
  - Directly-observed therapy (in-person or via telemedicine)
  - Patient navigators—trained staff who provide support to patients—educate patients to help them overcome barriers to taking their medicine.
- Primary outcome: SVR 12
- Secondary: Treatment initiation, adherence, and completion; Hep C re-infection
- February 2022

COMPARING WAYS TO PROVIDE HEPATITIS C TREATMENT FOR PEOPLE WHO TAKE METHADONE

- Delivery model for patients in methadone treatment
  - Telemedicine while they are at a methadone clinic
  - Usual care, in-person treatment from a liver specialist
- 12 methadone clinics in rural and urban areas in New York State
- Primary outcome: Viral response
- Secondary outcomes: Patient satisfaction with the delivery of care; rates of treatment completion; rates of relapse or re-infection
- Date not specified

Q&A

Please type your questions into the chat box.

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30

Thank you!

Your opinion is important to us. After the webinar ends, you will be redirected to a web page containing a **short survey**. Your answers to the survey will help us as we plan future NASHP webinars.

This webinar is supported by the Patient-Centered Outcomes Research Institute.

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31