Hepatitis C in the New Mexico Centennial Care Population: 2016 and Beyond

Centennial Care Medicaid Advisory Council
November 14, 2016 1:15 pm

David Scrase, M.D.

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Centennial Care's goal of treatment for hepatitis C is:

- *By 2020, to reduce morbidity and mortality by providing evidence-based treatment for all of our identifiable members with chronic hepatitis C infection, while being responsible fiscal stewards.*

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Agenda

- Introduction to Hepatitis C Virus
- HCV in the United States and New Mexico
- HCV in our Centennial Care population
  - Population model
  - Current treatment: patients and expenses vs. targets, based on encounter and prior auth data
- Action plan for 2016 and beyond

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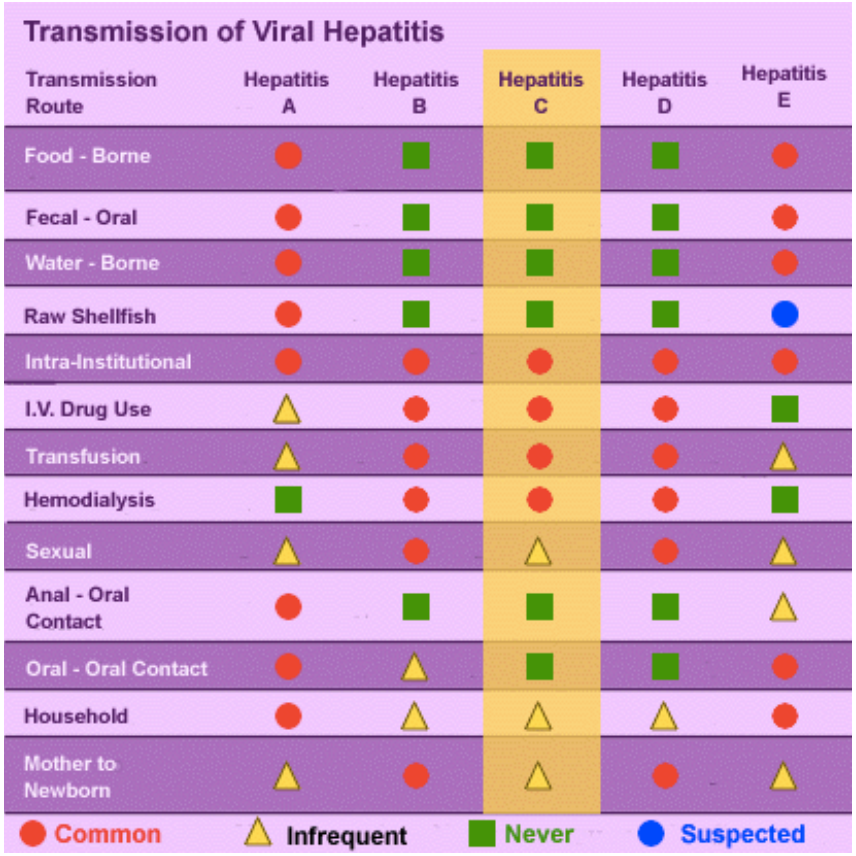
The Major Hepatitis Viruses

- Hepatitis A is generally transmitted in food and does not create chronic illness
- Hepatitis B and C are transmitted via blood products, IV drug use, hemodialysis
- Hepatitis D and E are rare



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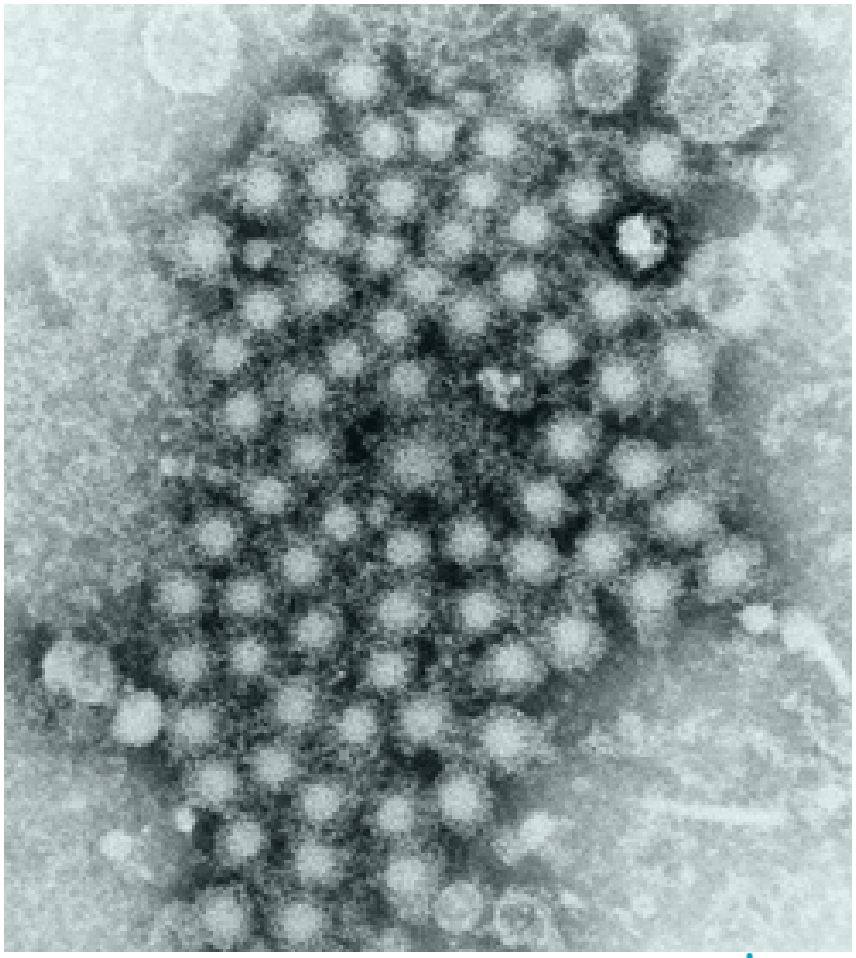
Hepatitis C Virus

- The third hepatitis virus, discovered in 1989
- Transmitted by:
  - Healthcare exposure = 55% (especially common in “baby boomers” born between 1/1/1945 and 12/31/1965)
  - Intravenous drug use = 40%
  - Men having sex with men (MSM) = 5%



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Hepatitis C Genotypes

- Prominent genotypes vary geographically
- In the United States there are 2.7 – 4.0 M people with chronic HCV infection:
  - Genotype 1 = 70%
    - 1a = 55%
    - 1b = 15%
  - Genotype 2 = 19%
  - Genotype 3 = 10%
  - Genotype 4-6 = 1%

Region	Predominant HCV genotype
Europe, North America, Japan	Genotype 1a, 1b (genotypes 2 & 3 are less common)
Southeast Asia	Genotype 3
Egypt, the Middle East, Central Africa	Genotype 4
South Africa	Genotype 5
Asia	Genotype 6

http://www.hepatitisc.uw.edu/go/screening-diagnosis/epidemiology-us/core-concept/all

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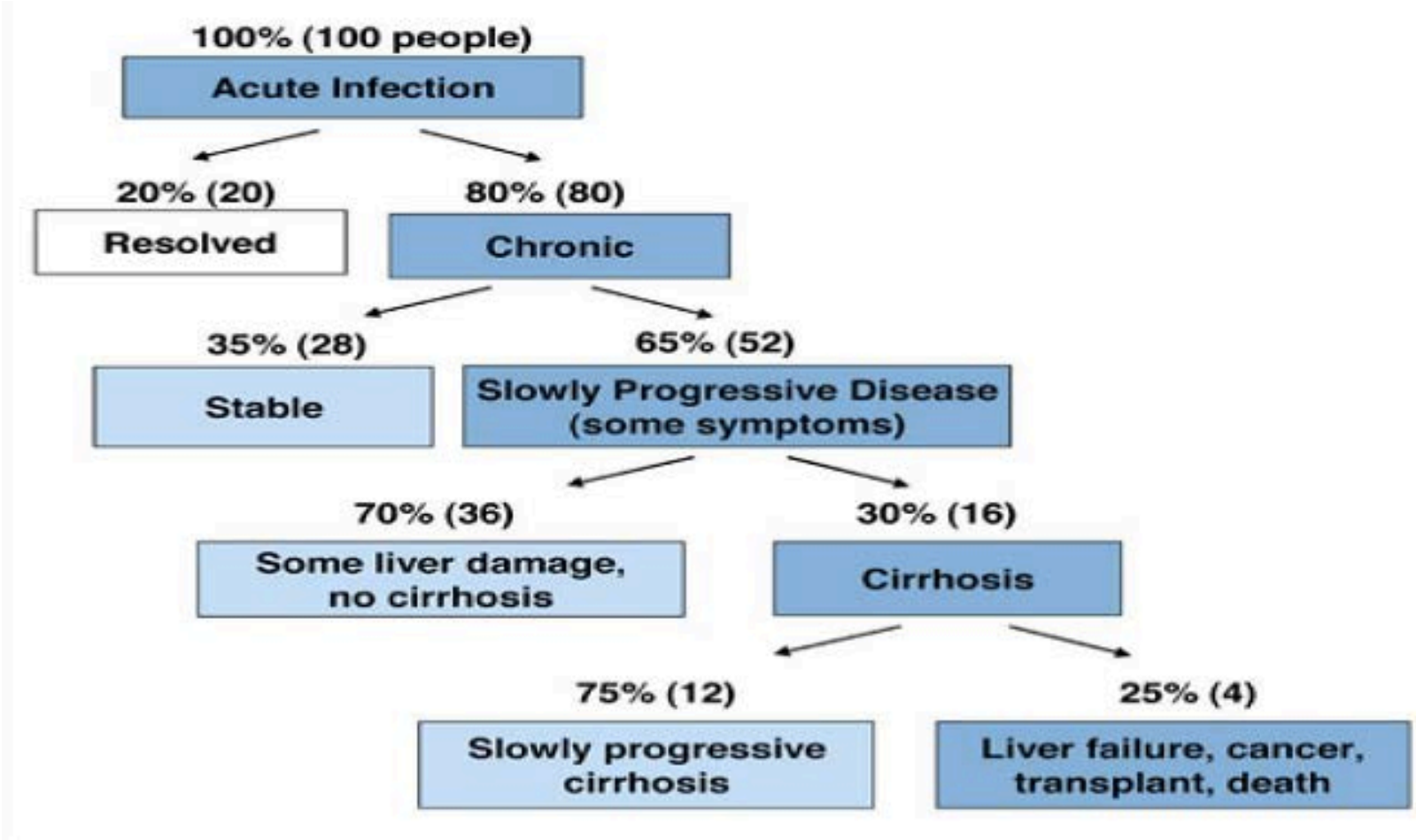
HCV Disease Progression over 10 – 25 Years (single infection)



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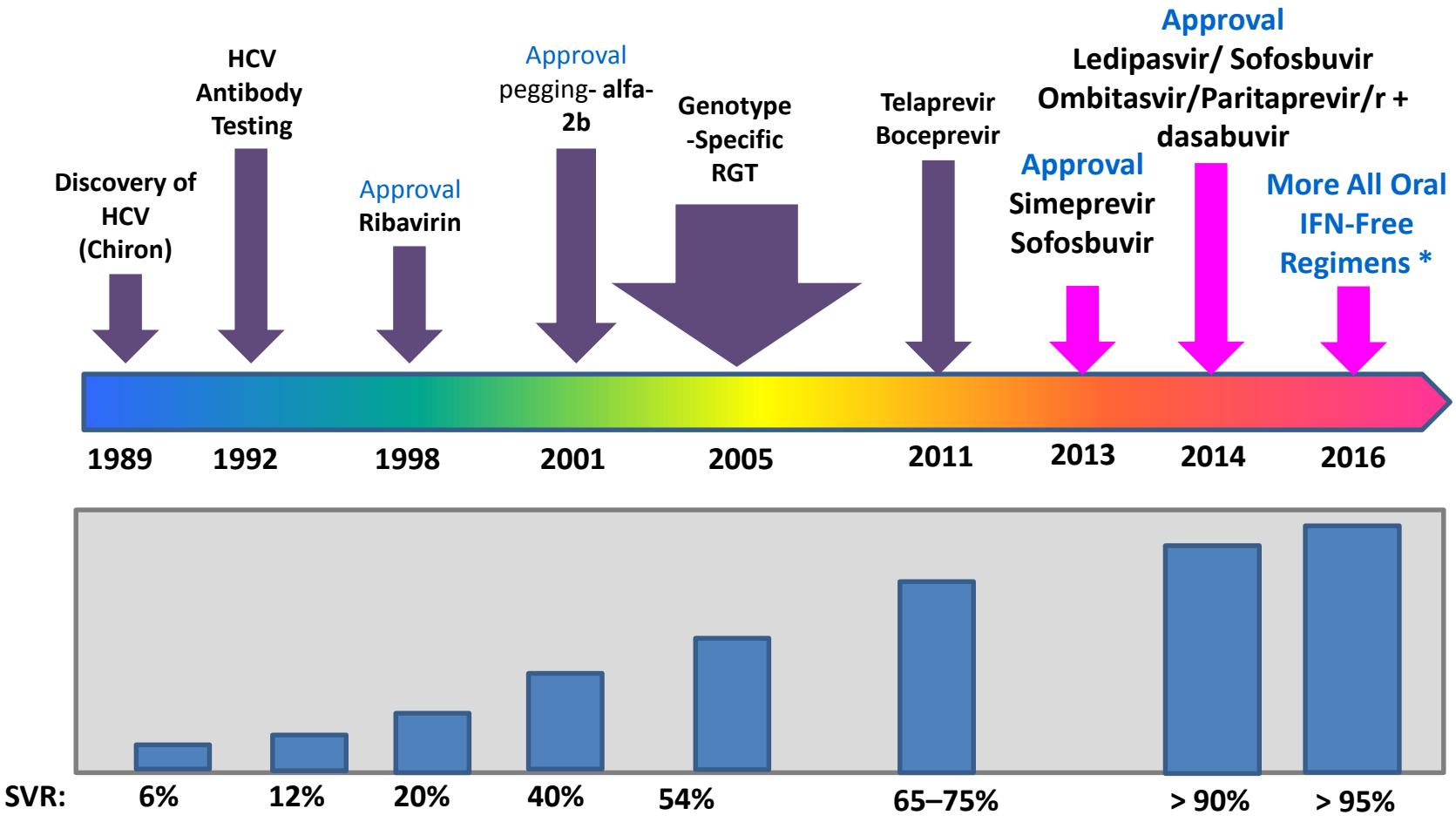
HCV Therapy: A Revolution



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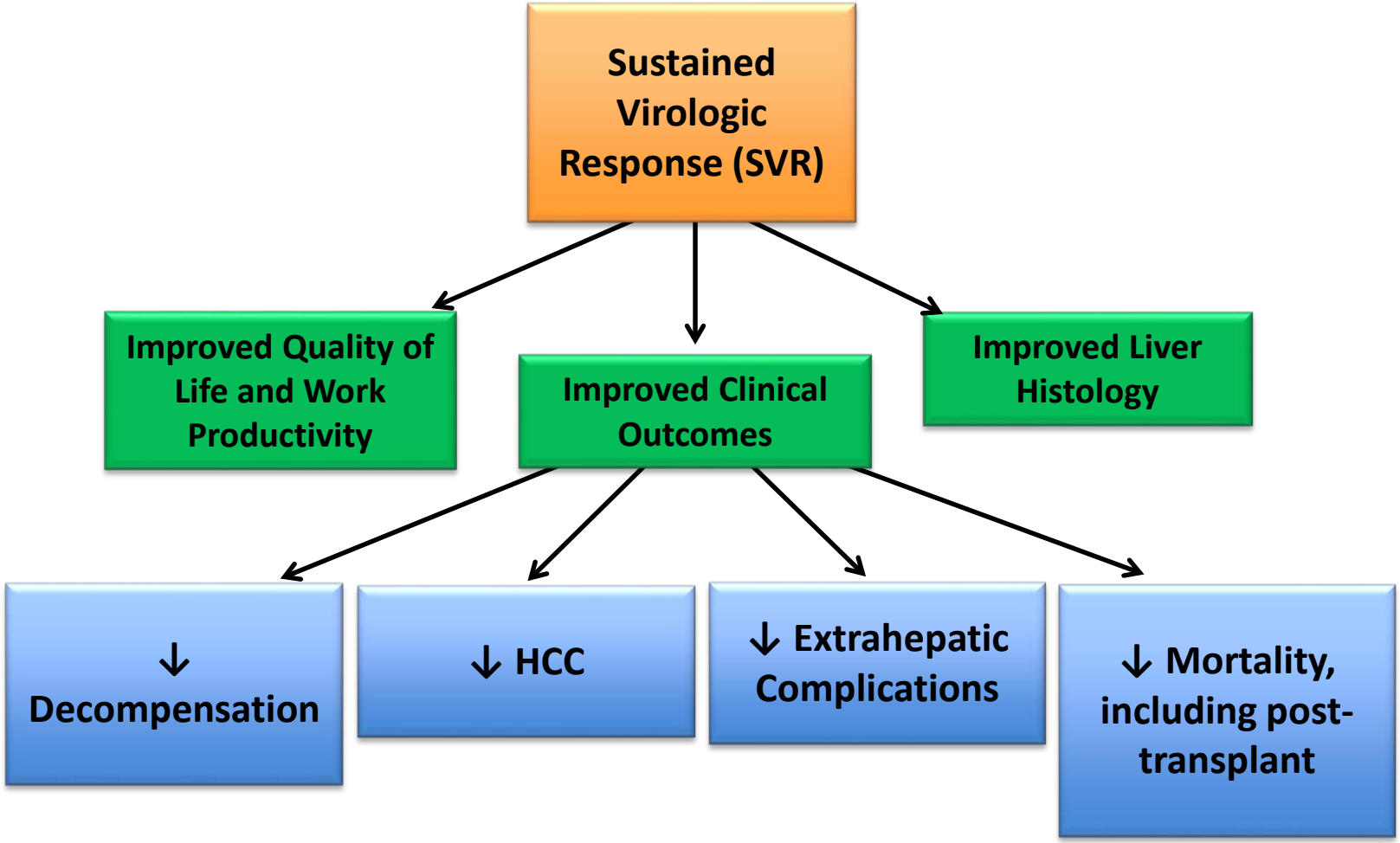
HCV Viral Eradication Yields Many Benefits



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All Oral Therapy Has Many Advantages over Intravenous Treatment

- Minimal pre-testing needed
- Low intensity of monitoring
- Side effects more easily managed
- High efficacy across a broad spectrum of patients
- No injections
- Well-tolerated
- Short duration
- High success

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The Backlog Problem

- Because of the lack of effective treatment that could be tolerated, a large backlog of patients needing treatment has accumulated.
- Unfortunately, the majority of these patients are in advanced stages of liver disease.

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HCV in the United States and New Mexico

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Quiz: What group has the majority of Hepatitis C infections in America?

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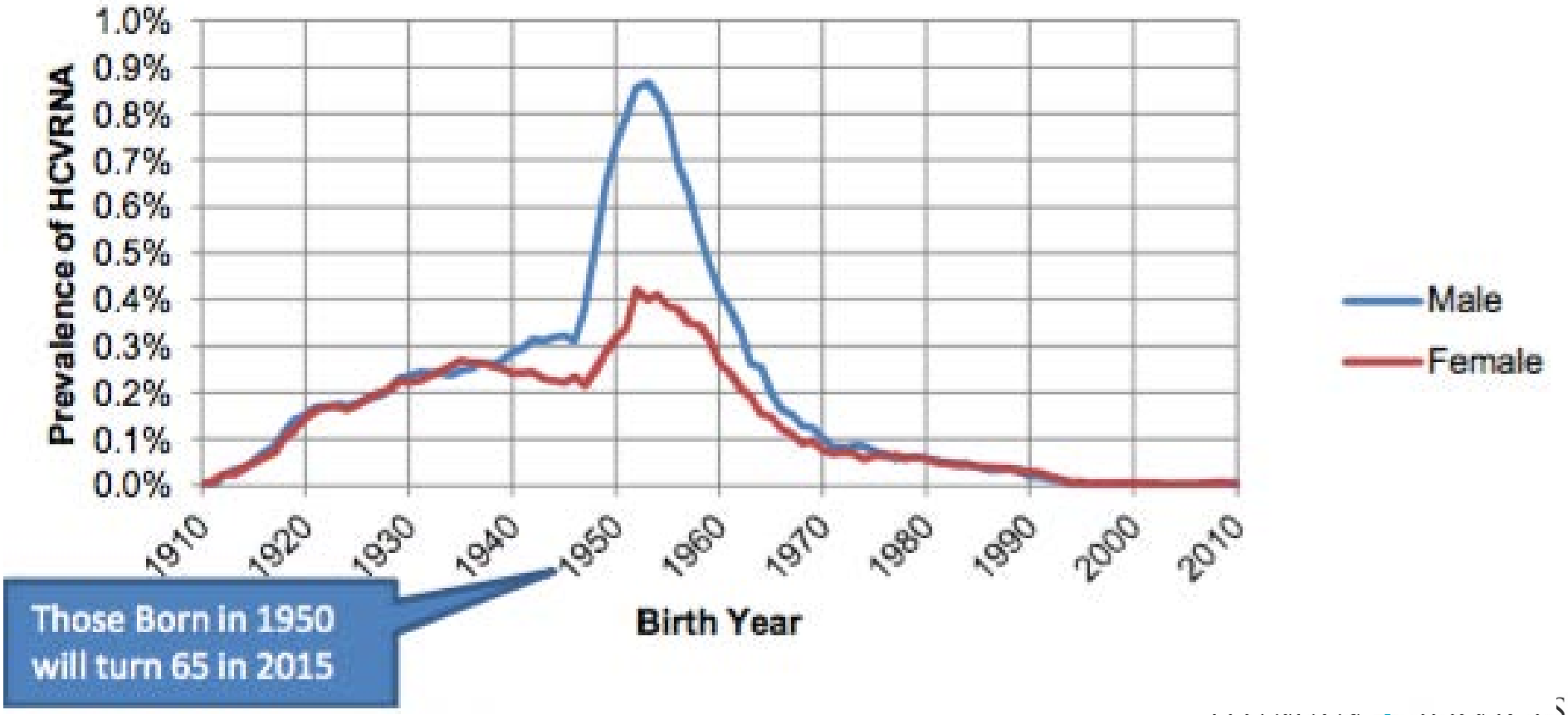
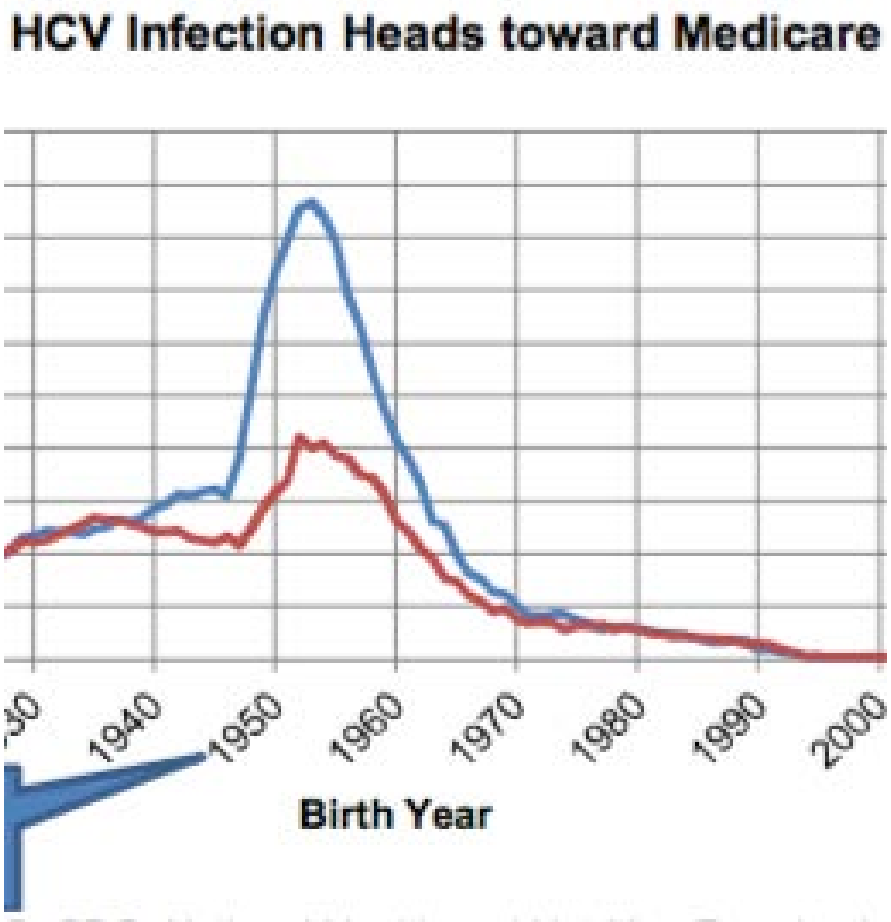
The wave of HCV Infection heads toward Medicare eligibility

Milliman 2013: **Health Care Reform and Hepatitis C: Convergence of Risk and Opportunity** (analysis of NHANES, MarketScan 2010, Medicare 5% Sample, and Medicaid Contributor data. Does not include prison population).



Quiz on Hepatitis C

- I think that the US cost of treating those "bumps" in the curves to the right will be
  - $165 thousand
  - $165 million
  - $165 billion
  - $165 trillion



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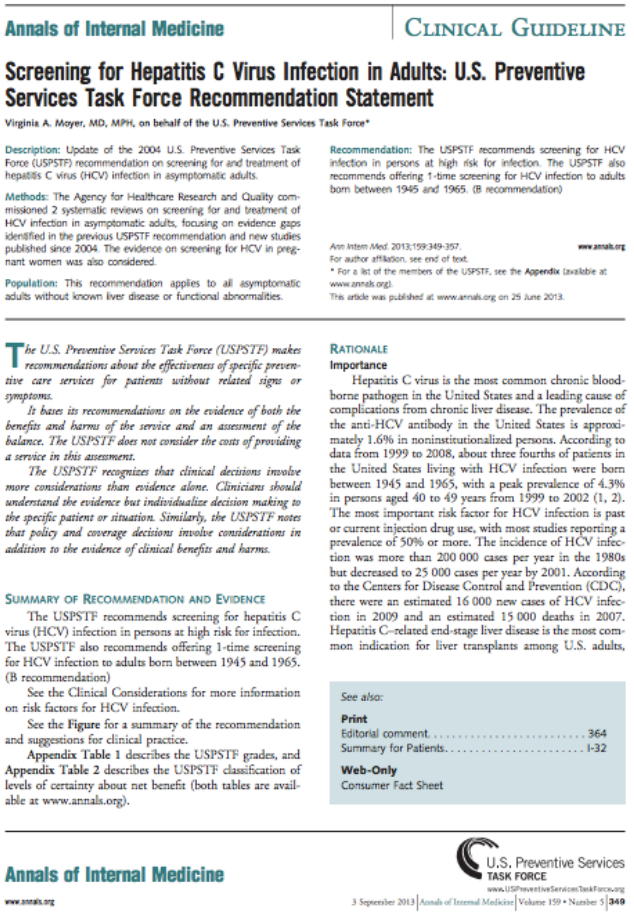
2013 Screening Recommendations from the US Preventive Services Task Force and CDC

- Screen those born between 1/1/1945 and 12/31/1965 because the incidence of chronic HCV infection is twice as high
- Only 50% of have history of
  - Blood transfusion
  - Sexual exposure
  - IV drug use
  - “Non-professional” tattoo



Annals of Internal Medicine | CLINICAL GUIDELINE

Screening for Hepatitis C Virus Infection in Adults: U.S. Preventive Services Task Force Recommendation Statement

Virginia A. Moyer, MD, MPH, on behalf of the U.S. Preventive Services Task Force*

Description: Update of the 2004 U.S. Preventive Services Task Force (USPSTF) recommendation on screening for and treatment of hepatitis C virus (HCV) infection in asymptomatic adults.

Methods: The Agency for Healthcare Research and Quality commissioned 2 systematic reviews on screening for and treatment of HCV infection in asymptomatic adults, focusing on evidence gaps identified in the previous USPSTF recommendation and new studies published since 2004. The evidence on screening for HCV in pregnant women was also considered.

Population: This recommendation applies to all asymptomatic adults without known liver disease or functional abnormalities.

Recommendation: The USPSTF recommends screening for HCV infection in persons at high risk for infection. The USPSTF also recommends offering 1-time screening for HCV infection to adults born between 1945 and 1965. (B recommendation)

Ann Intern Med. 2013;159:349-357. www.annals.org

For author affiliation, see end of text.

* For a list of the members of the USPSTF, see the **Appendix** (available at www.annals.org).

This article was published at www.annals.org on 25 June 2013.

The U.S. Preventive Services Task Force (USPSTF) makes recommendations about the effectiveness of specific preventive care services for patients without related signs or symptoms.

It bases its recommendations on the evidence of both the benefits and harms of the service and an assessment of the balance. The USPSTF does not consider the costs of providing a service in this assessment.

The USPSTF recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decision making to the specific patient or situation. Similarly, the USPSTF notes that policy and coverage decisions involve considerations in addition to the evidence of clinical benefits and harms.

SUMMARY OF RECOMMENDATION AND EVIDENCE

The USPSTF recommends screening for hepatitis C virus (HCV) infection in persons at high risk for infection. The USPSTF also recommends offering 1-time screening for HCV infection to adults born between 1945 and 1965. (B recommendation)

See the Clinical Considerations for more information on risk factors for HCV infection.

See the **Figure** for a summary of the recommendation and suggestions for clinical practice.

Appendix Table 1 describes the USPSTF grades, and **Appendix Table 2** describes the USPSTF classification of levels of certainty about net benefit (both tables are available at www.annals.org).

RATIONALE

Importance

Hepatitis C virus is the most common chronic bloodborne pathogen in the United States and a leading cause of complications from chronic liver disease. The prevalence of the anti-HCV antibody in the United States is approximately 1.6% in noninstitutionalized persons. According to data from 1999 to 2008, about three fourths of patients in the United States living with HCV infection were born between 1945 and 1965, with a peak prevalence of 4.3% in persons aged 40 to 49 years from 1999 to 2002 (1, 2). The most important risk factor for HCV infection is past or current injection drug use, with most studies reporting a prevalence of 50% or more. The incidence of HCV infection was more than 200 000 cases per year in the 1980s but decreased to 25 000 cases per year by 2001. According to the Centers for Disease Control and Prevention (CDC), there were an estimated 16 000 new cases of HCV infection in 2009 and an estimated 15 000 deaths in 2007. Hepatitis C–related end-stage liver disease is the most common indication for liver transplants among U.S. adults,

See also:

Print

Editorial comment. 364

Summary for Patients. I-32

Web-Only

Consumer Fact Sheet

Annals of Internal Medicine

www.annals.org

U.S. Preventive Services TASK FORCE

www.USPreventiveServicesTaskForce.org

3 September 2013 | Annals of Internal Medicine | Volume 159 • Number 5 | 349

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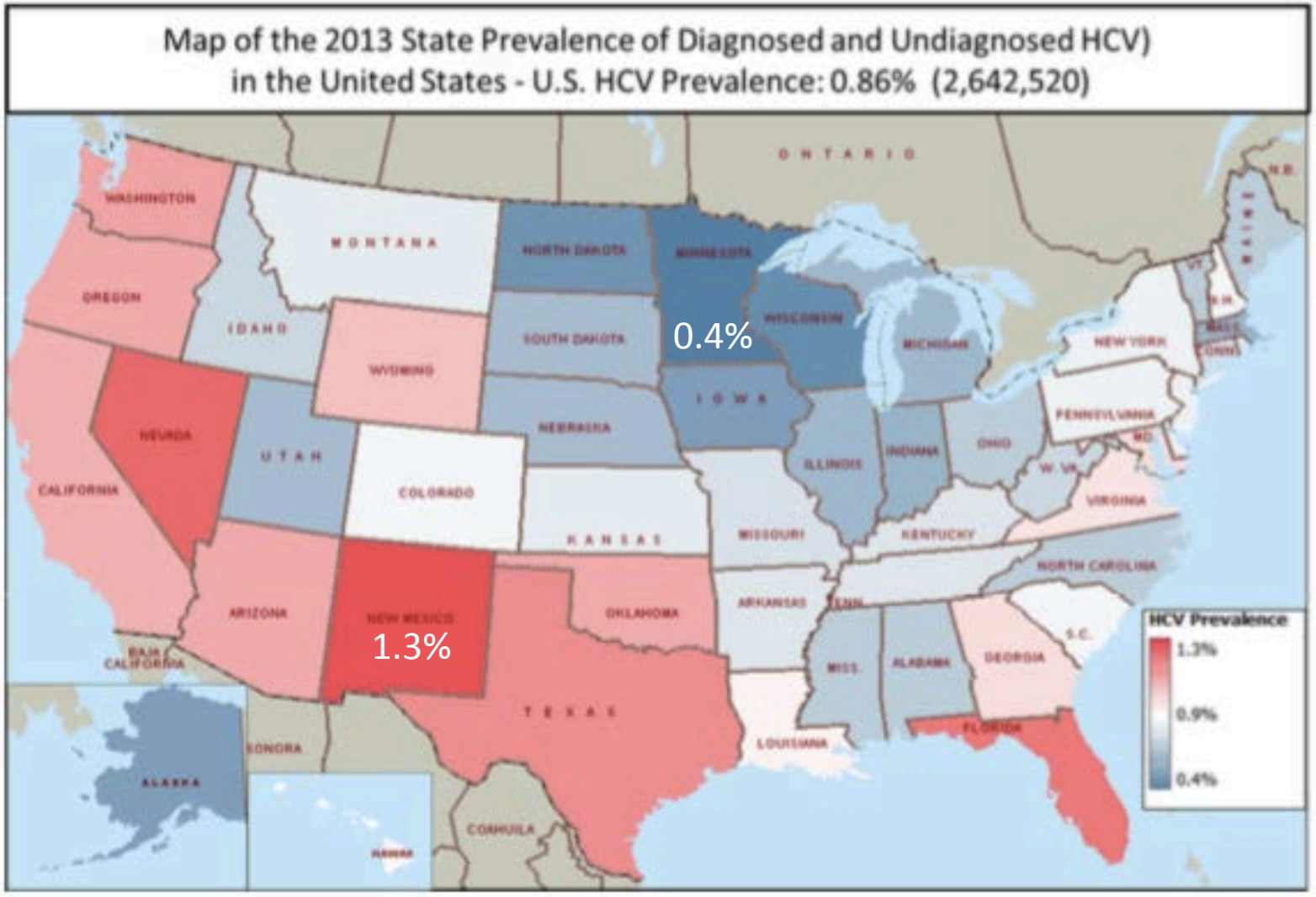
New Mexico has the highest prevalence of HCV in the US

Milliman 2013: **Health Care Reform and Hepatitis C: Convergence of Risk and Opportunity** (analysis of NHANES, MarketScan 2010, Medicare 5% Sample, and Medicaid Contributor data. Does not include prison population).



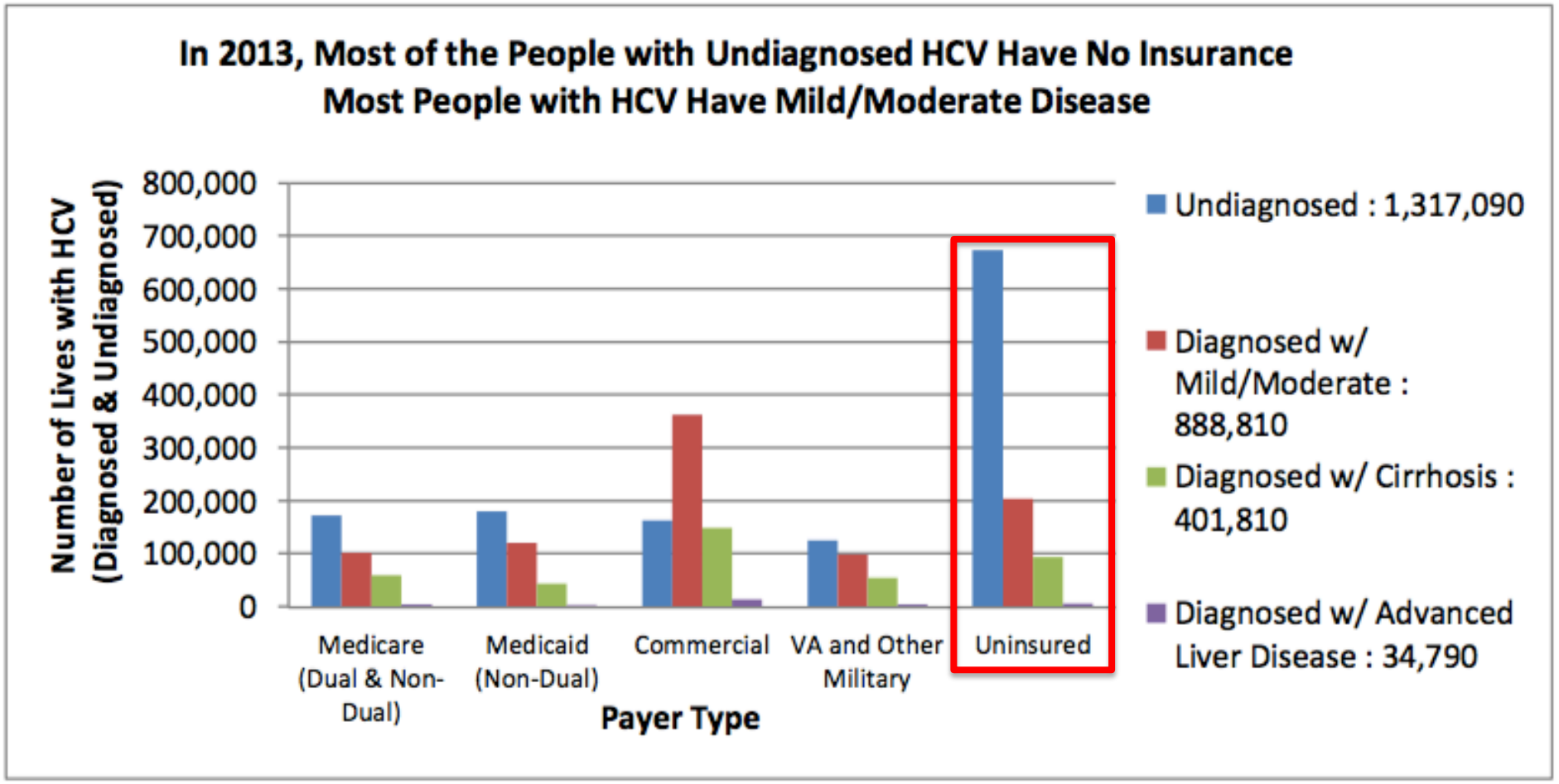
2013 HCV Prevalence by Health Insurance Type

Milliman 2013: **Health Care Reform and Hepatitis C: Convergence of Risk and Opportunity**
(analysis of NHANES, MarketScan 2010, Medicare 5% Sample, and Medicaid Contributor data)

Health Insurance Type	Total U.S. Population (Thousands)	Estimated Prevalence of HCV-RNA+	Estimated Number of HCV-RNA+ (Thousands)
Uninsured	48,600	2.08%	1,012
Veteran Affairs	5,600	5.40%	302
Commercial	164,200	0.47%	779
Dual Medicare and Medicaid	6,900	2.91%	201
Medicare (non dual)	37,600	0.31%	117
Medicaid	43,300	0.87%	377
Other Military	2,200	0.47%	10
Prison	1,500	30.0%	450
Total	**310,000**	**1.05%**	**3,249**
Total without Prison	**308,500**	**0.91%**	**2,799**

In 2013, half of HCV infected patients were undiagnosed and many were without insurance

Milliman 2013: **Health Care Reform and Hepatitis C: Convergence of Risk and Opportunity** (analysis of NHANES, MarketScan 2010, Medicare 5% Sample, and Medicaid Contributor data. Does not include prison population).



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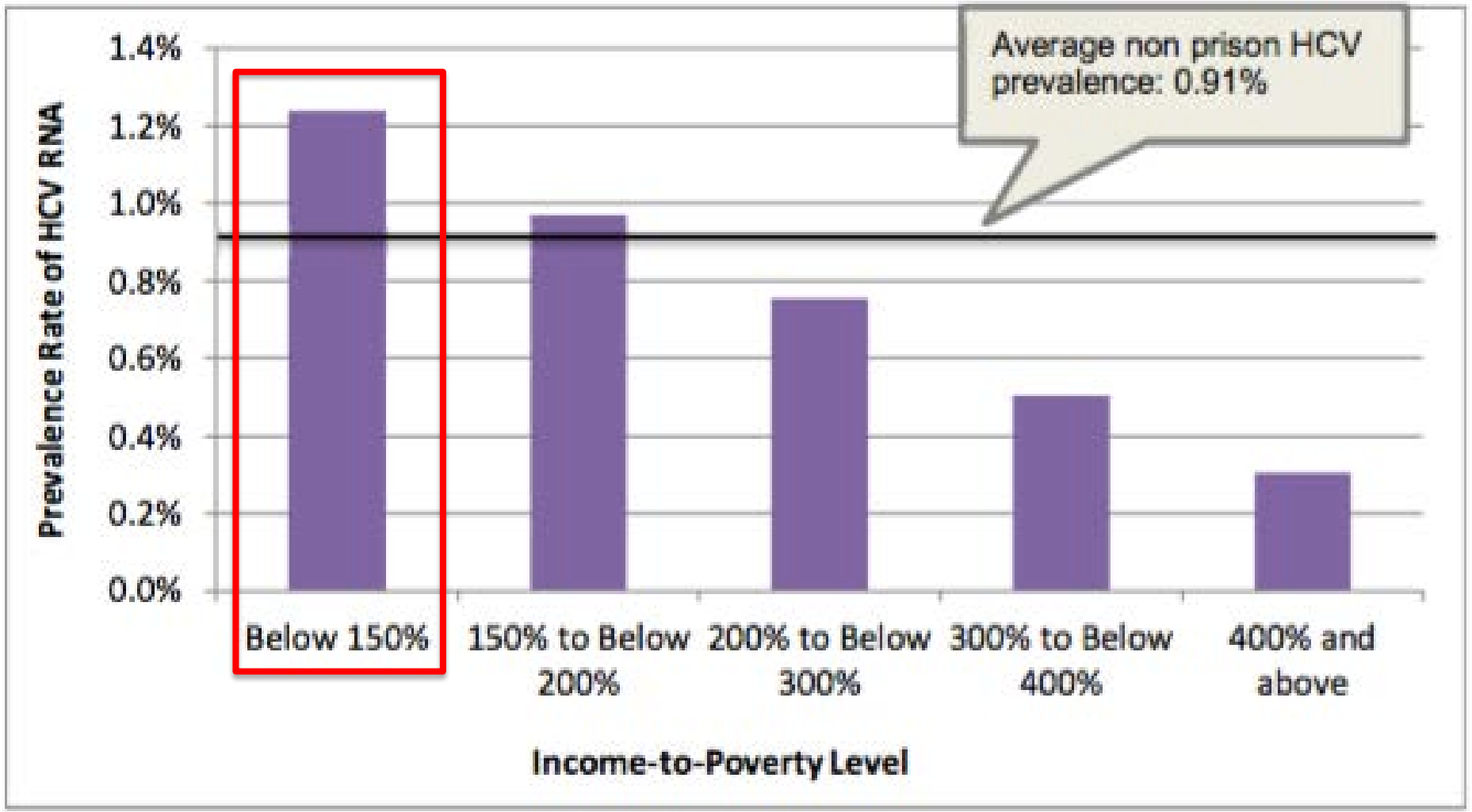
Prevalence of HCV is higher among lower-income individuals

Milliman 2013: **Health Care Reform and Hepatitis C: Convergence of Risk and Opportunity** (analysis of NHANES, MarketScan 2010, Medicare 5% Sample, and Medicaid Contributor data).



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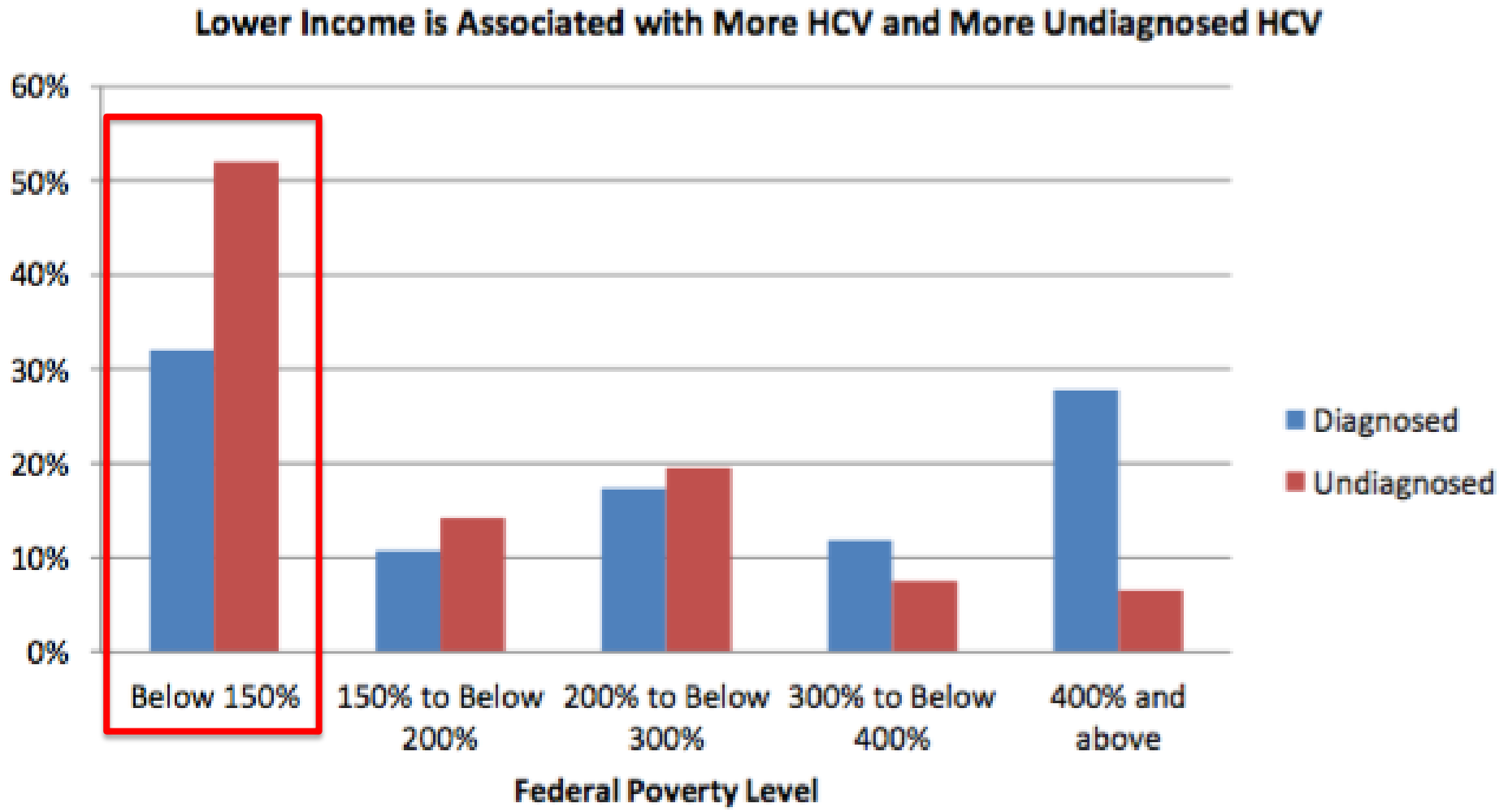
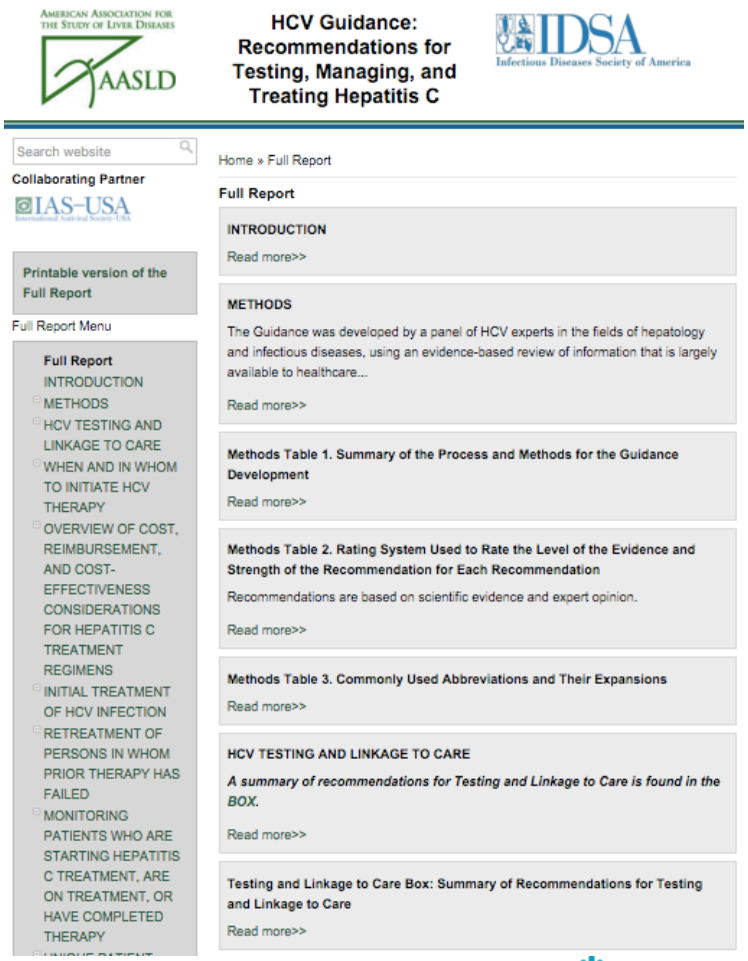
Portion of Diagnosed and Undiagnosed HCV Patients by Percent Federal Poverty Level

Milliman 2013: **Health Care Reform and Hepatitis C: Convergence of Risk and Opportunity** (analysis of NHANES, MarketScan 2010, Medicare 5% Sample, and Medicaid Contributor data).



HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C (at www.hcvguidelines.org)

- The American Association for the Study of Liver Diseases and the Infectious Disease Society of America (AASLD/IDSA) ***initially*** recommended treatment for ***high risk*** and ***highest risk HCV positive individuals*** *(about 25-30% of all Americans who are HCV positive).*



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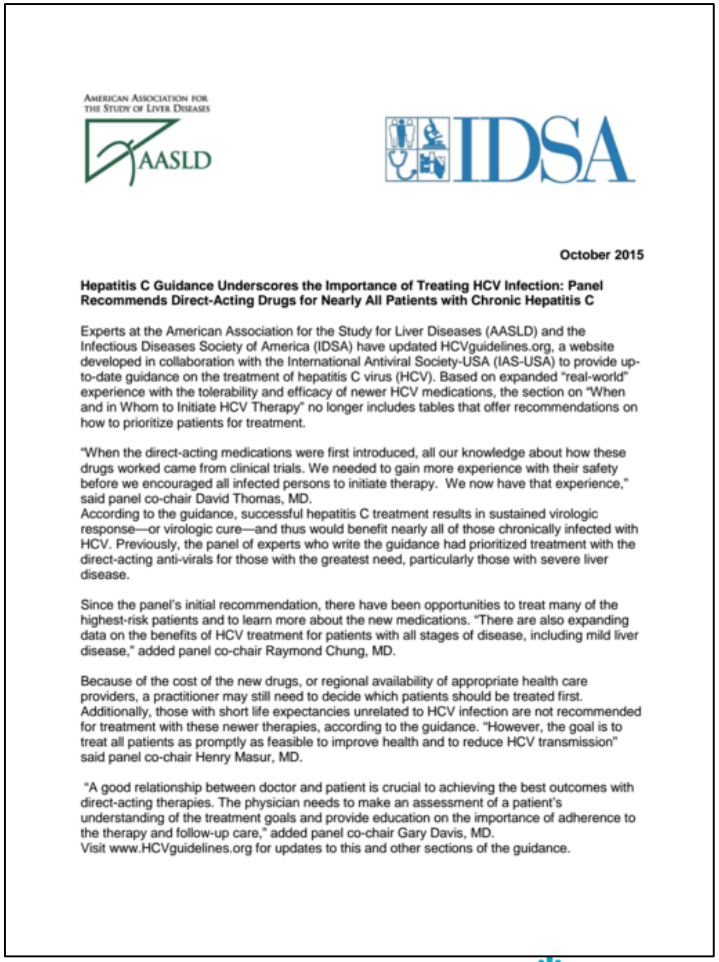
National attention focused on new guidelines: Treat Everyone!

HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C at www.hcvguidelines.org

- However, in October of 2015, AASLD/IDSA issued this press release recommending treatment for ***all "3 to 4 million Americans"*** **with chronic HCV infection**
- The cost for such treatment nationally will be ***~ $400 billion***



American Association for the Study of Liver Diseases AASLD IDSA

October 2015

Hepatitis C Guidance Underscores the Importance of Treating HCV Infection: Panel Recommends Direct-Acting Drugs for Nearly All Patients with Chronic Hepatitis C

Experts at the American Association for the Study for Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA) have updated HCVguidelines.org, a website developed in collaboration with the International Antiviral Society-USA (IAS-USA) to provide up-to-date guidance on the treatment of hepatitis C virus (HCV). Based on expanded "real-world" experience with the tolerability and efficacy of newer HCV medications, the section on "When and in Whom to Initiate HCV Therapy" no longer includes tables that offer recommendations on how to prioritize patients for treatment.

"When the direct-acting medications were first introduced, all our knowledge about how these drugs worked came from clinical trials. We needed to gain more experience with their safety before we encouraged all infected persons to initiate therapy. We now have that experience," said panel co-chair David Thomas, MD.
According to the guidance, successful hepatitis C treatment results in sustained virologic response—or virologic cure—and thus would benefit nearly all of those chronically infected with HCV. Previously, the panel of experts who write the guidance had prioritized treatment with the direct-acting anti-virals for those with the greatest need, particularly those with severe liver disease.

Since the panel's initial recommendation, there have been opportunities to treat many of the highest-risk patients and to learn more about the new medications. "There are also expanding data on the benefits of HCV treatment for patients with all stages of disease, including mild liver disease," added panel co-chair Raymond Chung, MD.

Because of the cost of the new drugs, or regional availability of appropriate health care providers, a practitioner may still need to decide which patients should be treated first. Additionally, those with short life expectancies unrelated to HCV infection are not recommended for treatment with these newer therapies, according to the guidance. "However, the goal is to treat all patients as promptly as feasible to improve health and to reduce HCV transmission" said panel co-chair Henry Masur, MD.

"A good relationship between doctor and patient is crucial to achieving the best outcomes with direct-acting therapies. The physician needs to make an assessment of a patient's understanding of the treatment goals and provide education on the importance of adherence to the therapy and follow-up care," added panel co-chair Gary Davis, MD.
Visit www.HCVguidelines.org for updates to this and other sections of the guidance.

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National attention focused on new guidelines: Treat Everyone!

HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C at www.hcvguidelines.org

Population Group	Number of Chronic HCV	Estimated Cost to Treat
United States	"3 – 4 million"	$300 - $400 billion
New Mexico	~35,000	~$3.5 billion
Centennial Care	10,000 – 15,000	$1.0 - $1.5 billion

Since the budgets of each of the above entities cannot bear the cost of treatment of *all these patients all at once*, what are the appropriate policy decisions to effectively treat all patients over time?

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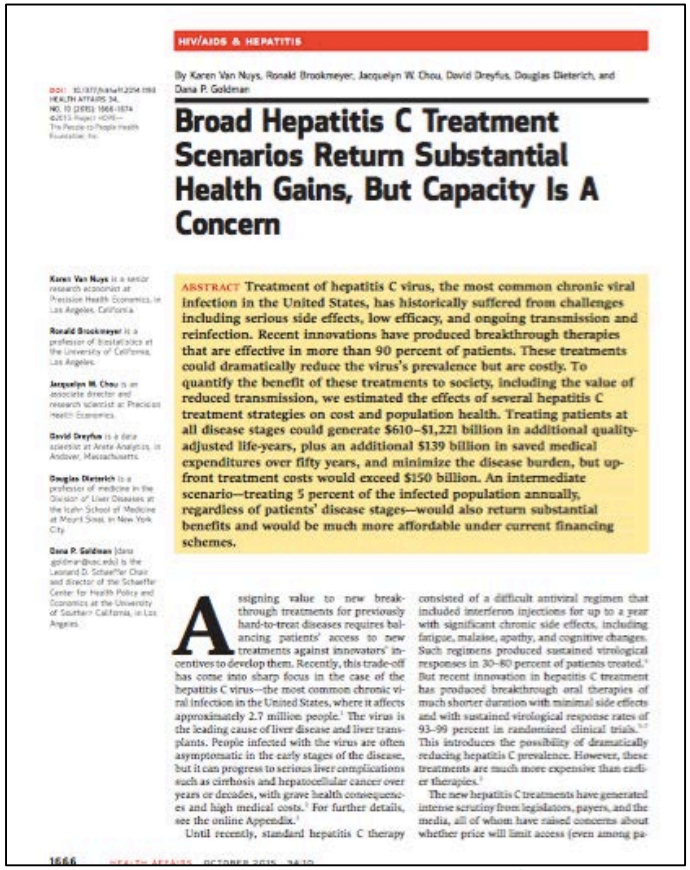
The Benefits of Earlier Treatment

Van Nuys K, Brookmeyer R, Chou JW, *et al.* **Broad Hepatitis C Treatment Scenarios Return Substantial Health Gains, But Capacity Is A Concern**. Health Affairs, 34, no.10 (2015):1666-1674.

- October 2015 study from *Health Affairs*, in which the authors modeled three (of many possible) scenarios for the treatment of chronic HCV positive individuals
- Substantial long-term socio-economic benefit from treatment was established



HIV/AIDS & HEPATITIS

By Karen Van Nuys, Ronald Brookmeyer, Jacquelyn W. Chou, David Dreyfus, Douglas Dieterich, and Dana P. Goldman

Broad Hepatitis C Treatment Scenarios Return Substantial Health Gains, But Capacity Is A Concern

ABSTRACT Treatment of hepatitis C virus, the most common chronic viral infection in the United States, has historically suffered from challenges including serious side effects, low efficacy, and ongoing transmission and reinfection. Recent innovations have produced breakthrough therapies that are effective in more than 90 percent of patients. These treatments could dramatically reduce the virus's prevalence but are costly. To quantify the benefit of these treatments to society, including the value of reduced transmission, we estimated the effects of several hepatitis C treatment strategies on cost and population health. Treating patients at all disease stages could generate $610–$1,221 billion in additional quality-adjusted life-years, plus an additional $139 billion in saved medical expenditures over fifty years, and minimize the disease burden, but up-front treatment costs would exceed $150 billion. An intermediate scenario—treating 5 percent of the infected population annually, regardless of patients' disease stages—would also return substantial benefits and would be much more affordable under current financing schemes.

Assigning value to new breakthrough treatments for previously hard-to-treat diseases requires balancing patients' access to new treatments against innovators' incentives to develop them. Recently, this trade-off has come into sharp focus in the case of the hepatitis C virus—the most common chronic viral infection in the United States, where it affects approximately 2.7 million people.[1] The virus is the leading cause of liver disease and liver transplants. People infected with the virus are often asymptomatic in the early stages of the disease, but it can progress to serious liver complications such as cirrhosis and hepatocellular cancer over years or decades, with grave health consequences and high medical costs.[2] For further details, see the online Appendix.[3]

Until recently, standard hepatitis C therapy consisted of a difficult antiviral regimen that included interferon injections for up to a year with significant chronic side effects, including fatigue, malaise, apathy, and cognitive changes. Such regimens produced sustained virological responses in 30–80 percent of patients treated.[4] But recent innovation in hepatitis C treatment has produced breakthrough oral therapies of much shorter duration with minimal side effects and with sustained virological response rates of 93–99 percent in randomized clinical trials.[5–7] This introduces the possibility of dramatically reducing hepatitis C prevalence. However, these treatments are much more expensive than earlier therapies.[8]

The new hepatitis C treatments have generated intense scrutiny from legislators, payers, and the media, all of whom have raised concerns about whether price will limit access (even among pa-

1666 HEALTH AFFAIRS OCTOBER 2015 34:10

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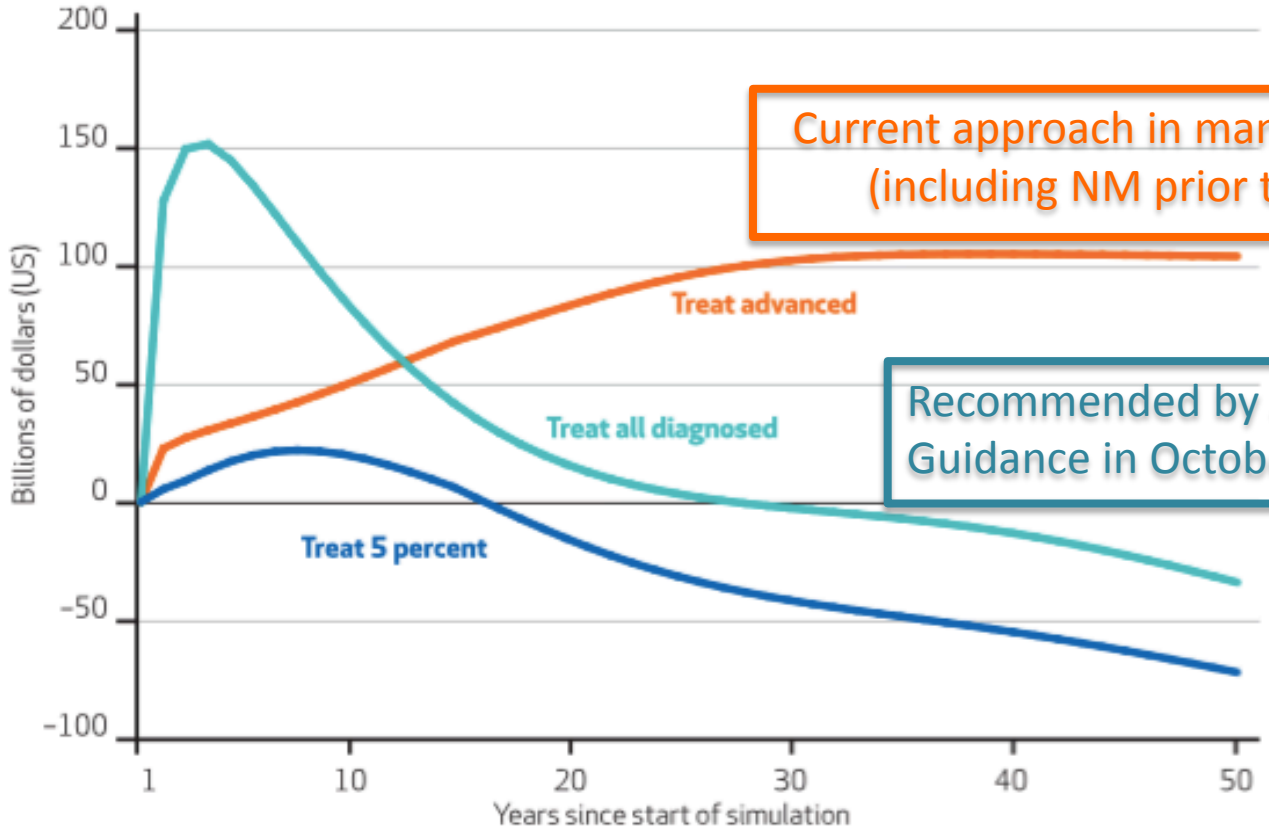
The Benefits of Earlier Treatment

Van Nuys K, Brookmeyer R, Chou JW, *et al.* **Broad Hepatitis C Treatment Scenarios Return Substantial Health Gains, But Capacity Is A Concern**. Health Affairs, 34, no.10 (2015):1666-1674.

Cumulative Hepatitis C Treatment And Nontreatment Medical Expenditures Net Of Baseline Expenditures In A 50-Year Simulation, By Treatment Scenario



Current approach in many Medicaid plans (including NM prior to 12/1/2015)

Recommended by AASLD/IDSA Guidance in October 2015

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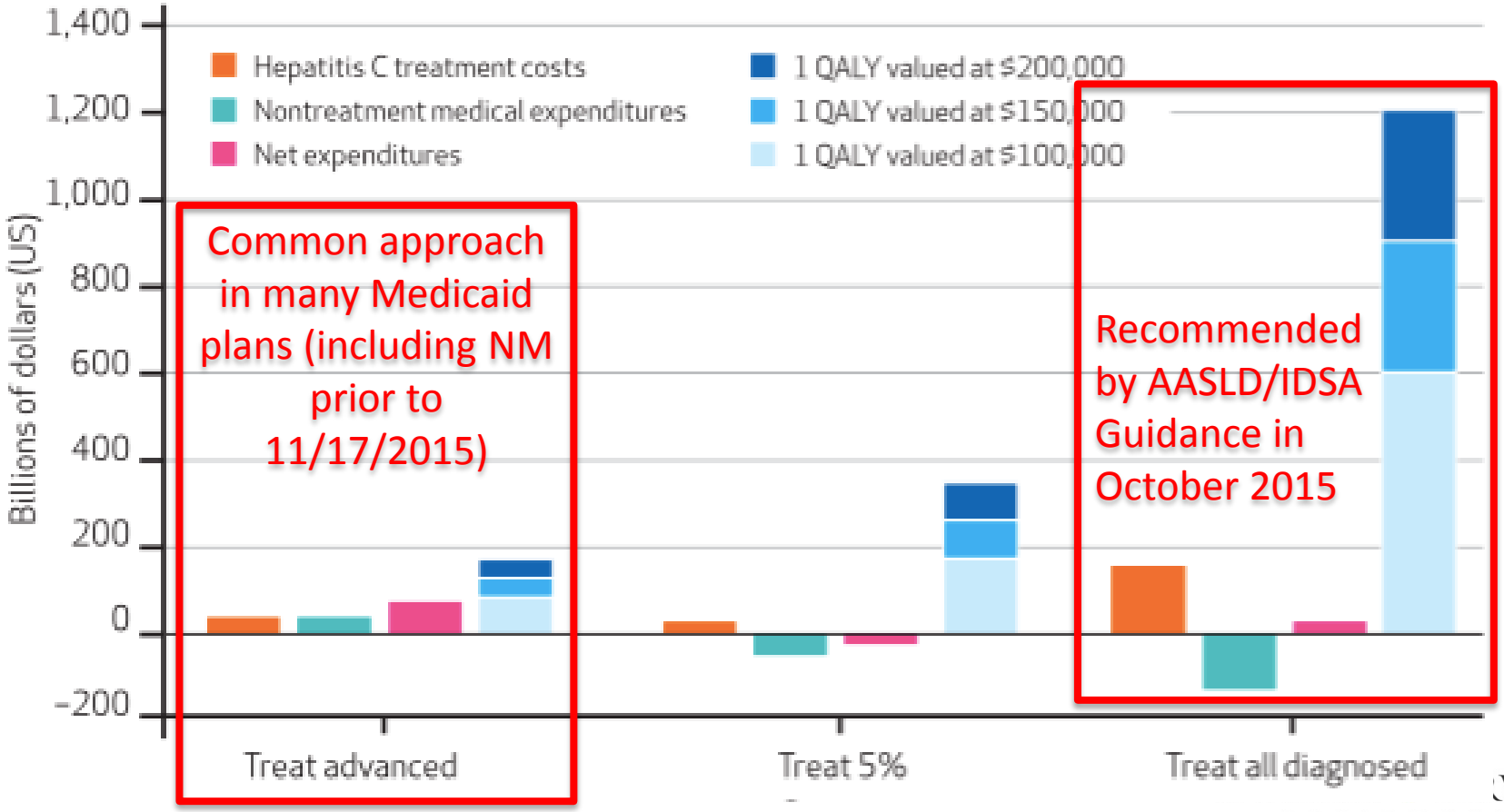
The Benefits of Earlier Treatment

Van Nuys K, Brookmeyer R, Chou JW, *et al.* **Broad Hepatitis C Treatment Scenarios Return Substantial Health Gains, But Capacity Is A Concern**. Health Affairs, 2015; 34 (10):1666-1674.

Cumulative Discounted Costs And Benefits Of Hepatitis C Treatment Strategies In A 50-Year Simulation Relative To Baseline, By Treatment Scenario



$1 Trillion Societal Benefit to Earlier Treatment

Van Nuys K, Brookmeyer R, Chou JW, *et al.* **Broad Hepatitis C Treatment Scenarios Return Substantial Health Gains, But Capacity Is A Concern**. Health Affairs, 34, no.10 (2015):1666-1674.

- "A policy of treating every patient with new agents, regardless of the extent of his or her liver damage, would generate $0.8–$1.5 trillion in total social value … or roughly **ten times the social value of treating only patients with advanced disease**."

- Over fifty years:
  - *$0.6–$1.2 trillion from improved health*
  - *$139 billion from reduced medical spending by preventing costly liver damage*
  - $100-200 billion in manufacturers' profits

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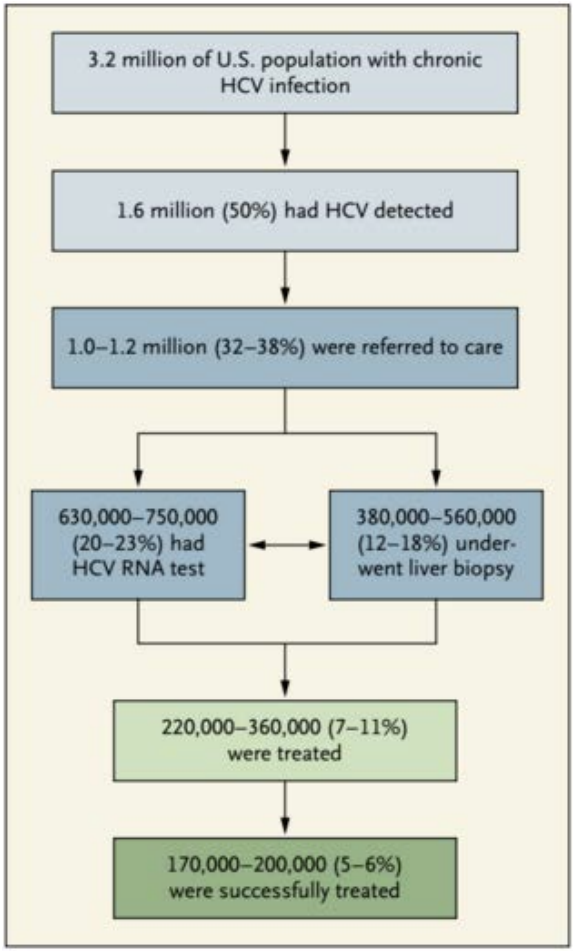
The Challenge to Identify and Treat

Holmberg S, *et al*. **Hepatitis C in the United States**, N Engl J Med 2013; 368:1859-1861.

- The treatment of HCV in America has been a challenge, and prior experience has been poor due to the toxicity of the treatment regimens and their lack of efficacy
- It is expected that the oral treatments now available will result in a much higher percentage of patients being treated



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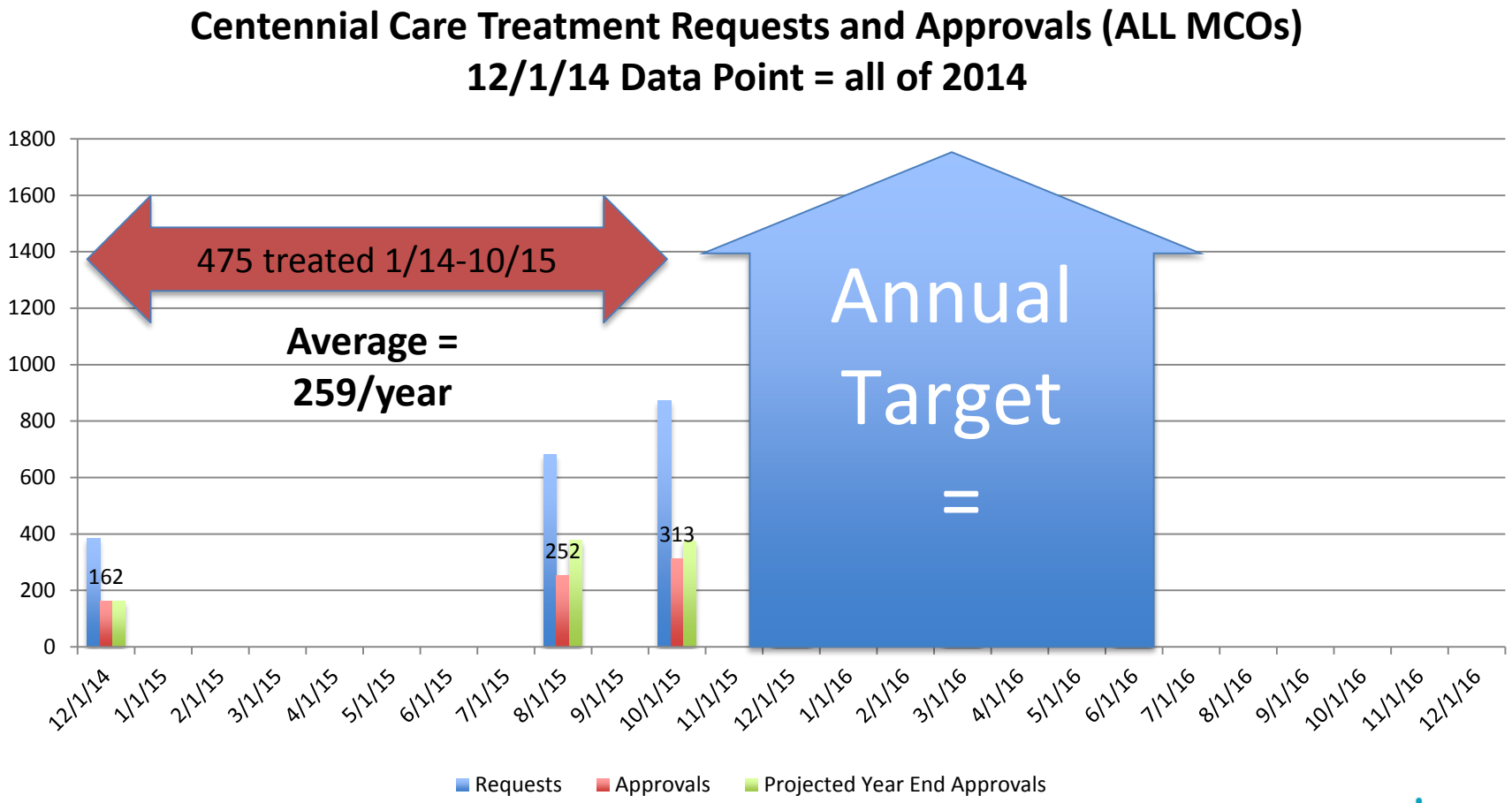
August 2015: Much Lower Centennial Care Approval Numbers than Planned



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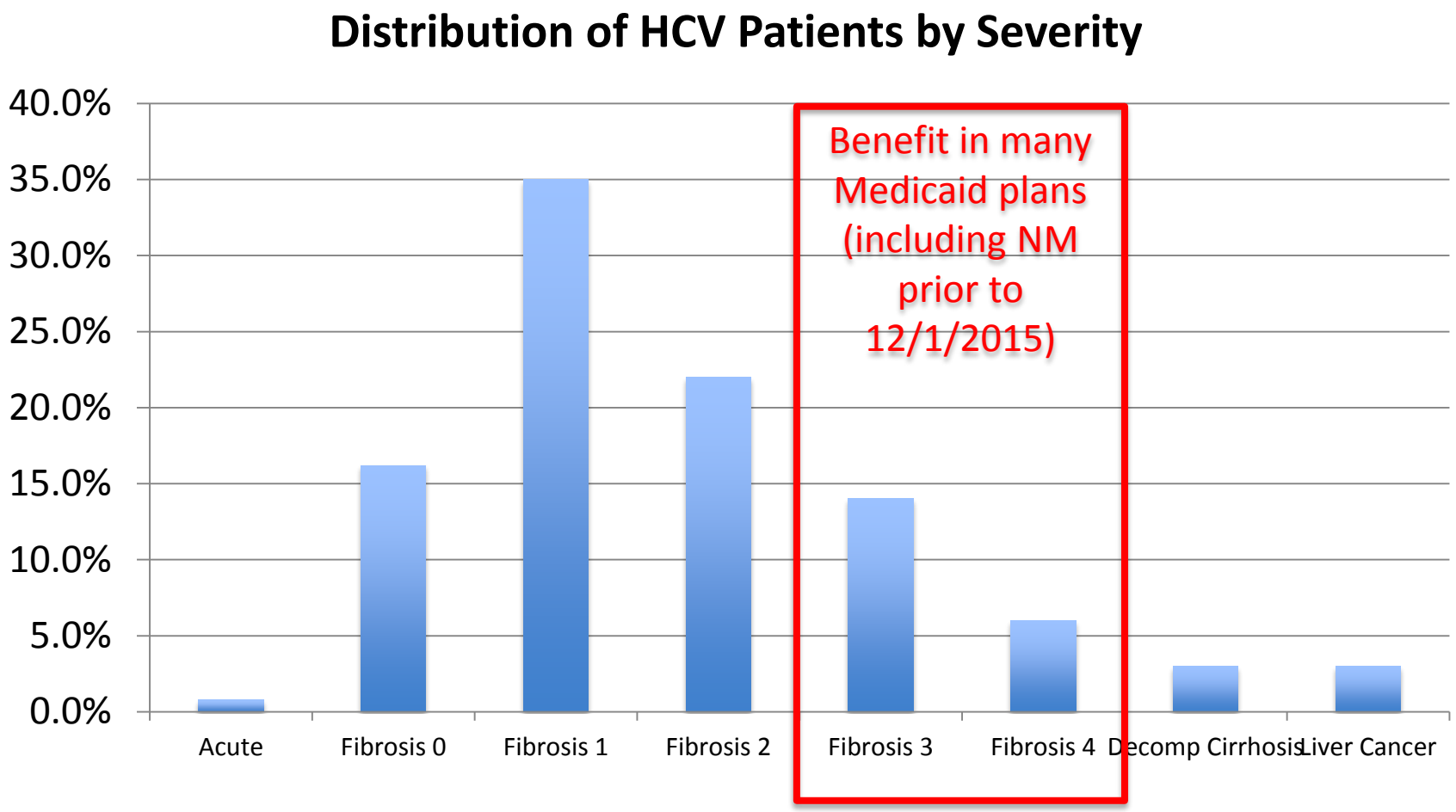
Hepatitis C in the US



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In October 2015: MAD Convenes MCOs to Increase Treatment Rates

- Centennial Care Goal presented: *By 2020, to reduce morbidity and mortality by providing evidence-based treatment for all of our identifiable members with chronic hepatitis C infection, while being responsible fiscal stewards.*
- Survey of Plans performed:
  - 4 hour meetings with each plan
  - Extensive review of approval processes and treatment data
  - Feedback received on proposed Letter of Direction with *very specific* treatment guidance

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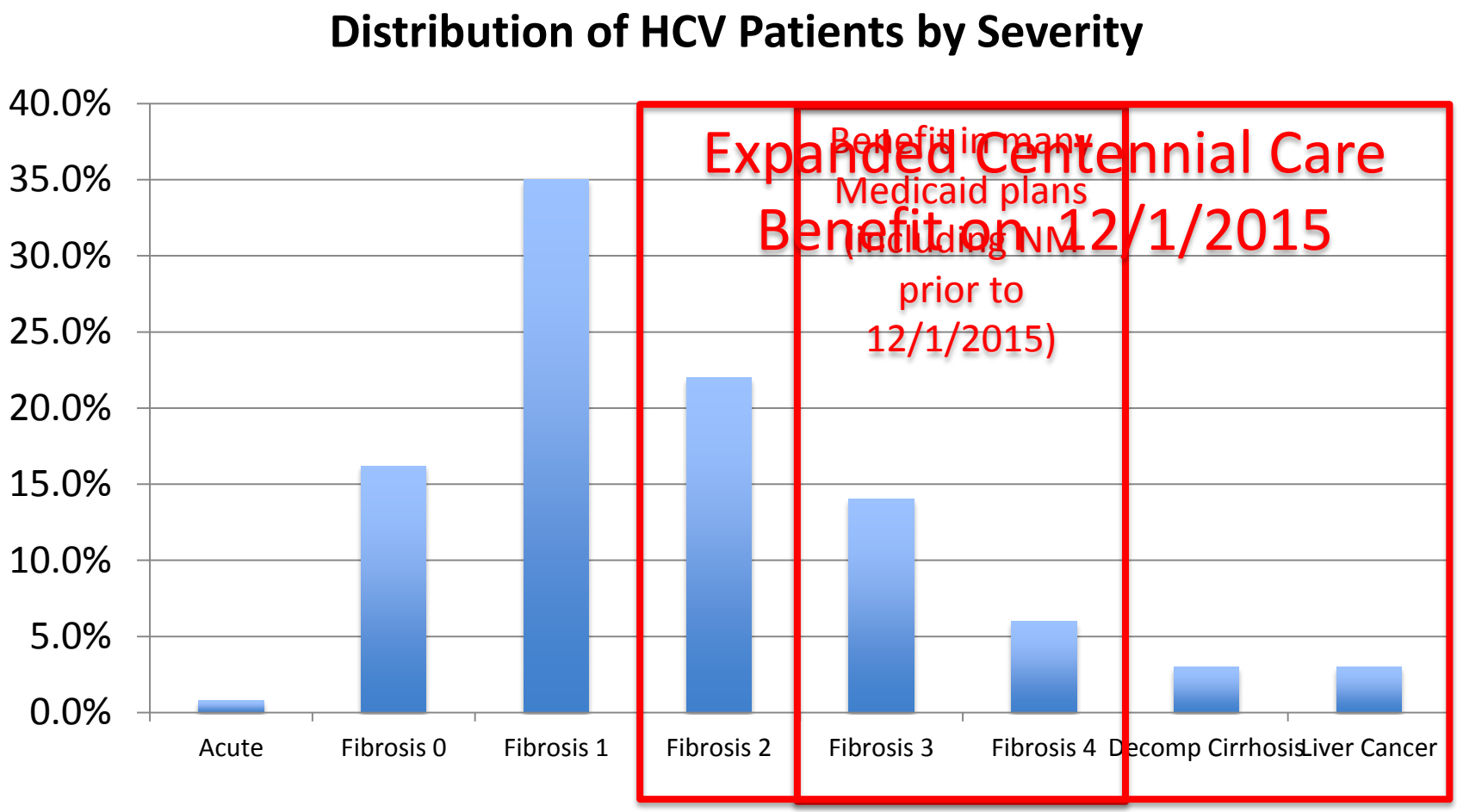
Hepatitis C in the US



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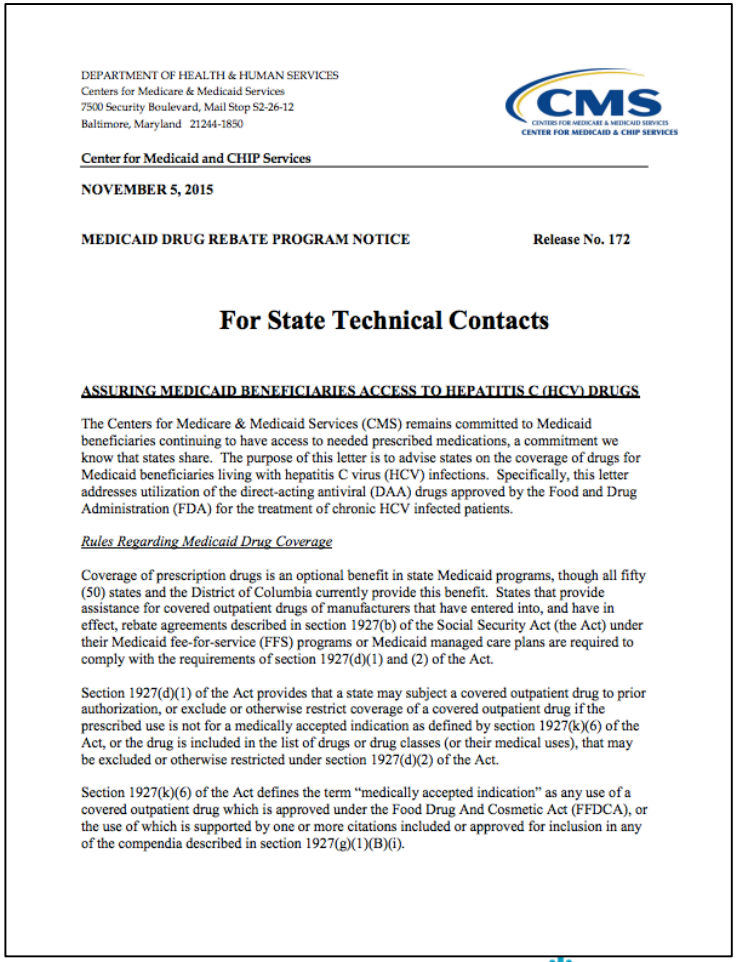
As we finalized our proposal, we received help from CMS in a November 5, 2015 Letter to States

- "Consistent with the regulation at 42 CFR §438.210, **services covered under Medicaid managed care contracts** (with MCOs, prepaid inpatient health plans, and prepaid ambulatory health plans) **must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services for beneficiaries under FFS Medicaid**."



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICAID & CHIP SERVICES

Center for Medicaid and CHIP Services

NOVEMBER 5, 2015

MEDICAID DRUG REBATE PROGRAM NOTICE Release No. 172

For State Technical Contacts

ASSURING MEDICAID BENEFICIARIES ACCESS TO HEPATITIS C (HCV) DRUGS

The Centers for Medicare & Medicaid Services (CMS) remains committed to Medicaid beneficiaries continuing to have access to needed prescribed medications, a commitment we know that states share. The purpose of this letter is to advise states on the coverage of drugs for Medicaid beneficiaries living with hepatitis C virus (HCV) infections. Specifically, this letter addresses utilization of the direct-acting antiviral (DAA) drugs approved by the Food and Drug Administration (FDA) for the treatment of chronic HCV infected patients.

Rules Regarding Medicaid Drug Coverage

Coverage of prescription drugs is an optional benefit in state Medicaid programs, though all fifty (50) states and the District of Columbia currently provide this benefit. States that provide assistance for covered outpatient drugs of manufacturers that have entered into, and have in effect, rebate agreements described in section 1927(b) of the Social Security Act (the Act) under their Medicaid fee-for-service (FFS) programs or Medicaid managed care plans are required to comply with the requirements of section 1927(d)(1) and (2) of the Act.

Section 1927(d)(1) of the Act provides that a state may subject a covered outpatient drug to prior authorization, or exclude or otherwise restrict coverage of a covered outpatient drug if the prescribed use is not for a medically accepted indication as defined by section 1927(k)(6) of the Act, or the drug is included in the list of drugs or drug classes (or their medical uses), that may be excluded or otherwise restricted under section 1927(d)(2) of the Act.

Section 1927(k)(6) of the Act defines the term "medically accepted indication" as any use of a covered outpatient drug which is approved under the Food Drug And Cosmetic Act (FFDCA), or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i).

HUMAN SERVICES DEPARTMENT

Comparison of CMS Letter to Centennial Care Plan

CMS Letter

- Can't restrict prescribing to specialists
- Can't deny treatment due to concurrent drug use
- Can't restrict treatment to only those with advanced disease
- Reference to AASLD/IDSA guidelines

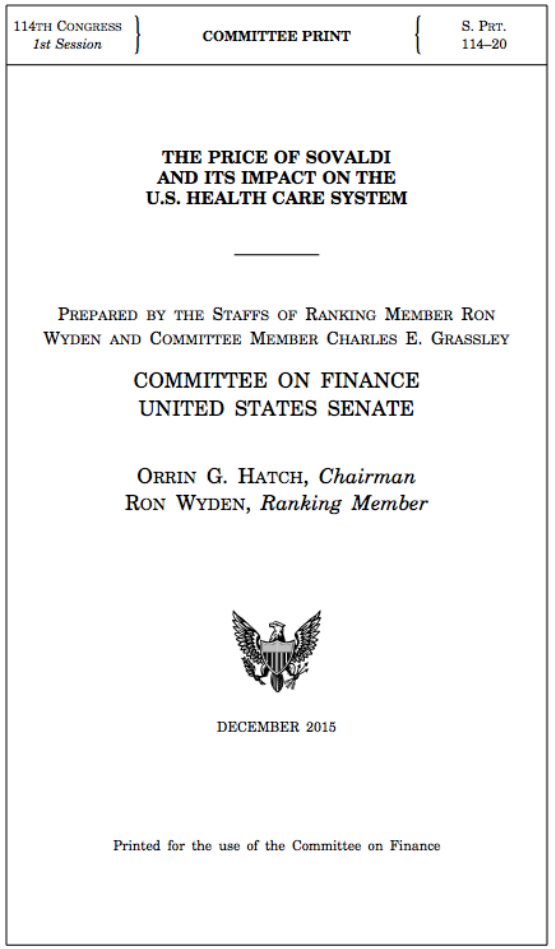
Centennial Care Plan

- Can't restrict prescribing to specialists
- Can't deny treatment due to concurrent drug use
- Expand treatment to the many more people (5 of 7 possible groups)
- Concern re some portions of AASLD/IDSA guidelines

HUMAN SERVICES DEPARTMENT

More "News" on HCV Drug Pricing from the Senate Finance Committee

December 1, 2015: "**WASHINGTON** – Senate Finance Committee Ranking Member Ron Wyden, D-Ore., and senior committee member Chuck Grassley, R-Iowa, today released the results of an 18-month investigation into the pricing and marketing of Gilead Sciences' Hepatitis C drug Sovaldi and its second-wave successor, Harvoni. Drawing from 20,000 pages of internal company documents, dozens of interviews with health care experts, and a trove of data from Medicaid programs in 50 states and the District of Columbia, **the investigation found that the company pursued a marketing strategy and final wholesale price of Sovaldi – $1,000 per pill, or $84,000 for a single course of treatment – that it believed would maximize revenue.** Building on that price, Harvoni was later introduced at $94,500. **Fostering broad, affordable access was not a key consideration in the process of setting the wholesale prices.**"



114TH CONGRESS *1st Session* | COMMITTEE PRINT | S. PRT. 114–20

THE PRICE OF SOVALDI AND ITS IMPACT ON THE U.S. HEALTH CARE SYSTEM

PREPARED BY THE STAFFS OF RANKING MEMBER RON WYDEN AND COMMITTEE MEMBER CHARLES E. GRASSLEY

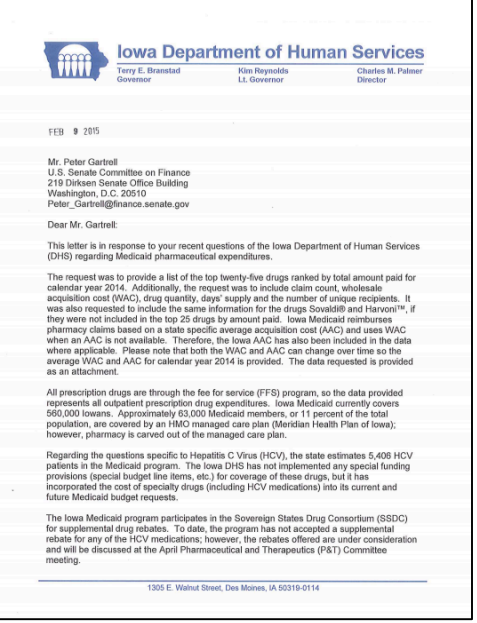
COMMITTEE ON FINANCE
UNITED STATES SENATE

ORRIN G. HATCH, *Chairman*
RON WYDEN, *Ranking Member*

DECEMBER 2015

Printed for the use of the Committee on Finance

HUMAN SERVICES DEPARTMENT



Iowa Department of Human Services

Terry E. Branstad, Governor · Kim Reynolds, Lt. Governor · Charles M. Palmer, Director

FEB 9 2015

Mr. Peter Gartrell
U.S. Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, D.C. 20510
Peter_Gartrell@finance.senate.gov

Dear Mr. Gartrell:

This letter is in response to your recent questions of the Iowa Department of Human Services (DHS) regarding Medicaid pharmaceutical expenditures.

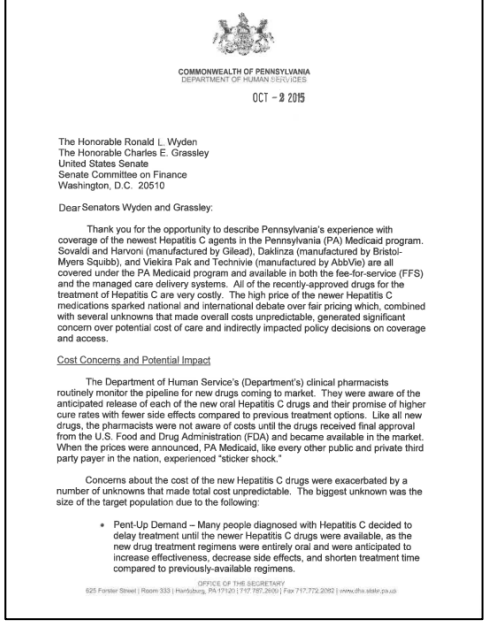
The request was to provide a list of the top twenty-five drugs ranked by total amount paid for calendar year 2014. Additionally, the request was to include claim count, wholesale acquisition cost (WAC), drug quantity, days' supply and the number of unique recipients. It was also requested to include the same information for the drugs Sovaldi® and Harvoni™, if they were not included in the top 25 drugs by amount paid. Iowa Medicaid reimburses pharmacy claims based on a state specific average acquisition cost (AAC) and uses WAC when an AAC is not available. Therefore, the Iowa AAC has also been included in the data where applicable. Please note that both the WAC and AAC can change over time so the average WAC and AAC for calendar year 2014 is provided. The data requested is provided as an attachment.

All prescription drugs are through the fee for service (FFS) program, so the data provided represents all outpatient prescription drug expenditures. Iowa Medicaid currently covers 560,000 Iowans. Approximately 63,000 Medicaid members, or 11 percent of the total population, are covered by an HMO managed care plan (Meridian Health Plan of Iowa); however, pharmacy is carved out of the managed care plan.

Regarding the questions specific to Hepatitis C Virus (HCV), the state estimates 5,406 HCV patients in the Medicaid program. The Iowa DHS has not implemented any special funding provisions (special budget line items, etc.) for coverage of these drugs, but it has incorporated the cost of specialty drugs (including HCV medications) into its current and future Medicaid budget requests.

The Iowa Medicaid program participates in the Sovereign States Drug Consortium (SSDC) for supplemental drug rebates. To date, the program has not accepted a supplemental rebate for any of the HCV medications; however, the rebates offered are under consideration and will be discussed at the April Pharmaceutical and Therapeutics (P&T) Committee meeting.

1305 E. Walnut Street, Des Moines, IA 50319-0114



COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF HUMAN SERVICES

OCT – 9 2015

The Honorable Ronald L. Wyden
The Honorable Charles E. Grassley
United States Senate
Senate Committee on Finance
Washington, D.C. 20510

Dear Senators Wyden and Grassley:

Thank you for the opportunity to describe Pennsylvania's experience with coverage of the newest Hepatitis C agents in the Pennsylvania (PA) Medicaid program. Sovaldi and Harvoni (manufactured by Gilead), Daklinza (manufactured by Bristol-Myers Squibb), and Viekira Pak and Technivie (manufactured by AbbVie) are all covered under the PA Medicaid program and available in both the fee-for-service (FFS) and the managed care delivery systems. All of the recently-approved drugs for the treatment of Hepatitis C are very costly. The high price of the newer Hepatitis C medications sparked national and international debate over fair pricing which, combined with several unknowns that made overall costs unpredictable, generated significant concern over potential cost of care and indirectly impacted policy decisions on coverage and access.

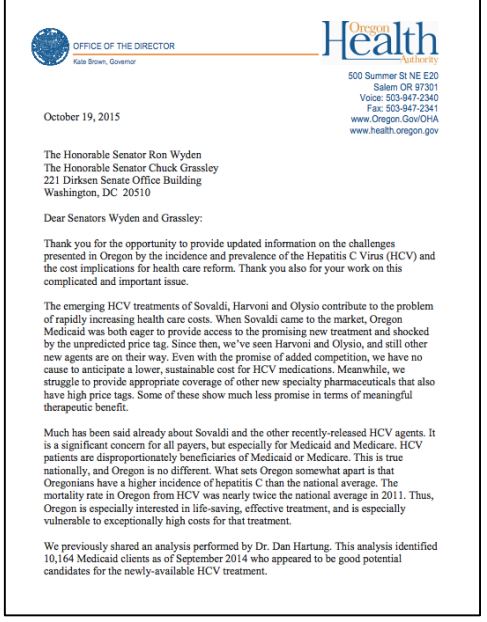
Cost Concerns and Potential Impact

The Department of Human Service's (Department's) clinical pharmacists routinely monitor the pipeline for new drugs coming to market. They were aware of the anticipated release of each of the new oral Hepatitis C drugs and their promise of higher cure rates with fewer side effects compared to previous treatment options. Like all new drugs, the pharmacists were not aware of costs until the drugs received final approval from the U.S. Food and Drug Administration (FDA) and became available in the market. When the prices were announced, PA Medicaid, like every other public and private third party payer in the nation, experienced "sticker shock."

Concerns about the cost of the new Hepatitis C drugs were exacerbated by a number of unknowns that made total cost unpredictable. The biggest unknown was the size of the target population due to the following:

- Pent-Up Demand – Many people diagnosed with Hepatitis C decided to delay treatment until the newer Hepatitis C drugs were available, as the new drug treatment regimens were entirely oral and were anticipated to increase effectiveness, decrease side effects, and shorten treatment time compared to previously-available regimens.

OFFICE OF THE SECRETARY
625 Forster Street | Room 333 | Harrisburg, PA 17120 | 717.787.2600 | Fax 717.772.2062 | www.dhs.state.pa.us



OFFICE OF THE DIRECTOR
Kate Brown, Governor

Oregon Health Authority

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Salem OR 97301
Voice: 503-947-2340
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www.Oregon.Gov/OHA
www.health.oregon.gov

October 19, 2015

The Honorable Senator Ron Wyden
The Honorable Senator Chuck Grassley
221 Dirksen Senate Office Building
Washington, DC 20510

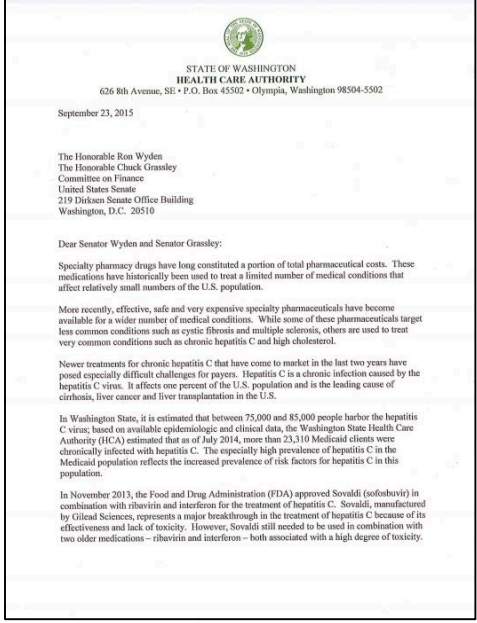
Dear Senators Wyden and Grassley:

Thank you for the opportunity to provide updated information on the challenges presented in Oregon by the incidence and prevalence of the Hepatitis C Virus (HCV) and the cost implications for health care reform. Thank you also for your work on this complicated and important issue.

The emerging HCV treatments of Sovaldi, Harvoni and Olysio contribute to the problem of rapidly increasing health care costs. When Sovaldi came to the market, Oregon Medicaid was both eager to provide access to the promising new treatment and shocked by the unpredicted price tag. Since then, we've seen Harvoni and Olysio, and still other new agents are on their way. Even with the promise of added competition, we have no cause to anticipate a lower, sustainable cost for HCV medications. Meanwhile, we struggle to provide appropriate coverage of other new specialty pharmaceuticals that also have high price tags. Some of these show much less promise in terms of meaningful therapeutic benefit.

Much has been said already about Sovaldi and the other recently-released HCV agents. It is a significant concern for all payers, but especially for Medicaid and Medicare. HCV patients are disproportionately beneficiaries of Medicaid or Medicare. This is true nationally, and Oregon is no different. What sets Oregon somewhat apart is that Oregonians have a higher incidence of hepatitis C than the national average. The mortality rate in Oregon from HCV was nearly twice the national average in 2011. Thus, Oregon is especially interested in life-saving, effective treatment, and is especially vulnerable to exceptionally high costs for that treatment.

We previously shared an analysis performed by Dr. Dan Hartung. This analysis identified 10,164 Medicaid clients as of September 2014 who appeared to be good potential candidates for the newly-available HCV treatment.



STATE OF WASHINGTON
HEALTH CARE AUTHORITY
626 8th Avenue, SE • P.O. Box 45502 • Olympia, Washington 98504-5502

September 23, 2015

The Honorable Ron Wyden
The Honorable Chuck Grassley
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Senator Wyden and Senator Grassley:

Specialty pharmacy drugs have long constituted a portion of total pharmaceutical costs. These medications have historically been used to treat a limited number of medical conditions that affect relatively small numbers of the U.S. population.

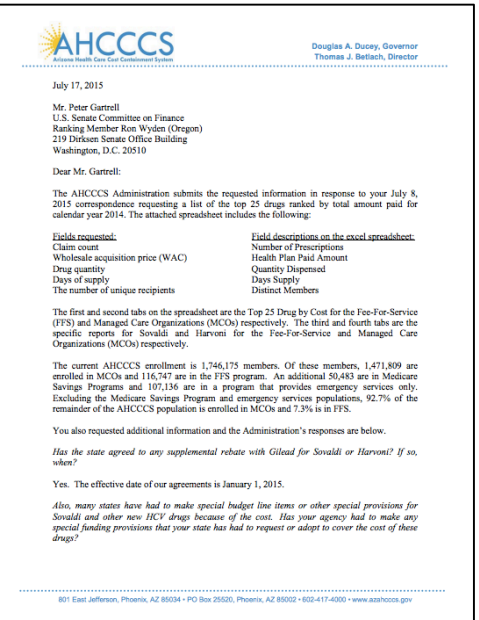
More recently, effective, safe and very expensive specialty pharmaceuticals have become available for a wider number of medical conditions. While some of these pharmaceuticals target less common conditions such as cystic fibrosis and multiple sclerosis, others are used to treat very common conditions such as chronic hepatitis C and high cholesterol.

Newer treatments for chronic hepatitis C that have come to market in the last two years have posed especially difficult challenges for payers. Hepatitis C is a chronic infection caused by the hepatitis C virus. It affects one percent of the U.S. population and is the leading cause of cirrhosis, liver cancer and liver transplantation in the U.S.

In Washington State, it is estimated that between 75,000 and 85,000 people harbor the hepatitis C virus; based on available epidemiologic and clinical data, the Washington State Health Care Authority (HCA) estimated that as of July 2014, more than 23,310 Medicaid clients were chronically infected with hepatitis C. The especially high prevalence of hepatitis C in the Medicaid population reflects the increased prevalence of risk factors for hepatitis C in this population.

In November 2013, the Food and Drug Administration (FDA) approved Sovaldi (sofosbuvir) in combination with ribavirin and interferon for the treatment of hepatitis C. Sovaldi, manufactured by Gilead Sciences, represents a major breakthrough in the treatment of hepatitis C because of its effectiveness and lack of toxicity. However, Sovaldi still needed to be used in combination with two older medications – ribavirin and interferon – both associated with a high degree of toxicity.

Letters from eight states to the Senate Finance Committee expressing concerns regarding the cost of treatment of new oral agents



AHCCCS
Arizona Health Care Cost Containment System

Douglas A. Ducey, Governor
Thomas J. Betlach, Director

July 17, 2015

Mr. Peter Gartrell
U.S. Senate Committee on Finance
Ranking Member Ron Wyden (Oregon)
219 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Mr. Gartrell:

The AHCCCS Administration submits the requested information in response to your July 8, 2015 correspondence requesting a list of the top 25 drugs ranked by total amount paid for calendar year 2014. The attached spreadsheet includes the following:

Fields requested:	Field descriptions on the excel spreadsheet:
Claim count	Number of Prescriptions
Wholesale acquisition price (WAC)	Health Plan Paid Amount
Drug quantity	Quantity Dispensed
Days of supply	Days Supply
The number of unique recipients	Distinct Members

The first and second tabs on the spreadsheet are the Top 25 Drug by Cost for the Fee-For-Service (FFS) and Managed Care Organizations (MCOs) respectively. The third and fourth tabs are the specific reports for Sovaldi and Harvoni for the Fee-For-Service and Managed Care Organizations (MCOs) respectively.

The current AHCCCS enrollment is 1,746,175 members. Of these members, 1,471,809 are enrolled in MCOs and 116,747 are in the FFS program. An additional 50,483 are in Medicare Savings Programs and 107,136 are in a program that provides emergency services only. Excluding the Medicare Savings Program and emergency services populations, 92.7% of the remainder of the AHCCCS population is enrolled in MCOs and 7.3% is in FFS.

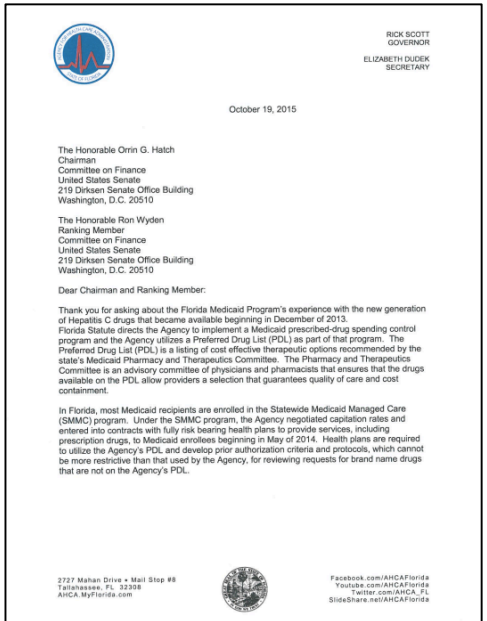
You also requested additional information and the Administration's responses are below.

Has the state agreed to any supplemental rebate with Gilead for Sovaldi or Harvoni? If so, when?

Yes. The effective date of our agreements is January 1, 2015.

Also, many states have had to make special budget line items or other special provisions for Sovaldi and other new HCV drugs because of the cost. Has your agency had to make any special funding provisions that your state has had to request or adopt to cover the cost of these drugs?

801 East Jefferson, Phoenix, AZ 85034 • PO Box 25520, Phoenix, AZ 85002 • 602-417-4000 • www.azahcccs.gov



RICK SCOTT
GOVERNOR

ELIZABETH DUDEK
SECRETARY

October 19, 2015

The Honorable Orrin G. Hatch
Chairman
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Chairman and Ranking Member:

Thank you for asking about the Florida Medicaid Program's experience with the new generation of Hepatitis C drugs that became available beginning in December of 2013. Florida Statute directs the Agency to implement a Medicaid prescribed-drug spending control program and the Agency utilizes a Preferred Drug List (PDL) as part of that program. The Preferred Drug List (PDL) is a listing of cost effective therapeutic options recommended by the state's Medicaid Pharmacy and Therapeutics Committee. The Pharmacy and Therapeutics Committee is an advisory committee of physicians and pharmacists that ensures that the drugs available on the PDL allow providers a selection that guarantees quality of care and cost containment.

In Florida, most Medicaid recipients are enrolled in the Statewide Medicaid Managed Care (SMMC) program. Under the SMMC program, the Agency negotiated capitation rates and entered into contracts with fully risk bearing health plans to provide services, including prescription drugs, to Medicaid enrollees beginning in May of 2014. Health plans are required to utilize the Agency's PDL and develop prior authorization criteria and protocols, which cannot be more restrictive than that used by the Agency, for reviewing requests for brand name drugs that are not on the Agency's PDL.

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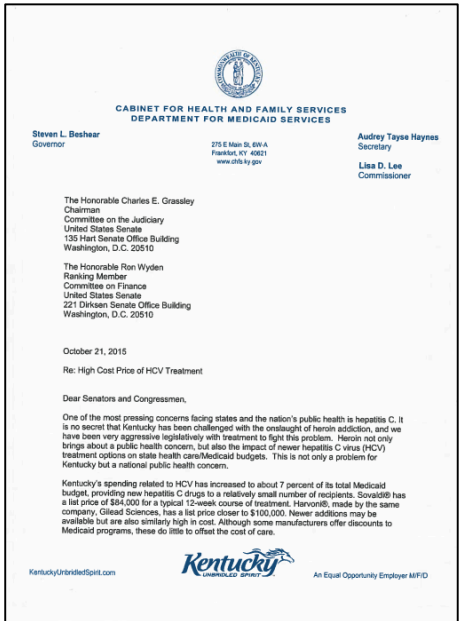

CABINET FOR HEALTH AND FAMILY SERVICES
DEPARTMENT FOR MEDICAID SERVICES

Steven L. Beshear
Governor

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Frankfort, KY 40621
www.chfs.ky.gov

Audrey Tayse Haynes
Secretary

Lisa D. Lee
Commissioner

The Honorable Charles E. Grassley
Chairman
Committee on the Judiciary
United States Senate
135 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate
221 Dirksen Senate Office Building
Washington, D.C. 20510

October 21, 2015

Re: High Cost Price of HCV Treatment

Dear Senators and Congressmen,

One of the most pressing concerns facing states and the nation's public health is hepatitis C. It is no secret that Kentucky has been challenged with the onslaught of heroin addiction, and we have been very aggressive legislatively with treatment to fight this problem. Heroin not only brings about a public health concern, but also the impact of newer hepatitis C virus (HCV) treatment options on state health care/Medicaid budgets. This is not only a problem for Kentucky but a national public health concern.

Kentucky's spending related to HCV has increased to about 7 percent of its total Medicaid budget, providing new hepatitis C drugs to a relatively small number of recipients. Sovaldi® has a list price of $84,000 for a typical 12-week course of treatment. Harvoni®, made by the same company, Gilead Sciences, has a list price closer to $100,000. Newer additions may be available but are also similarly high in cost. Although some manufacturers offer discounts to Medicaid programs, these do little to offset the cost of care.

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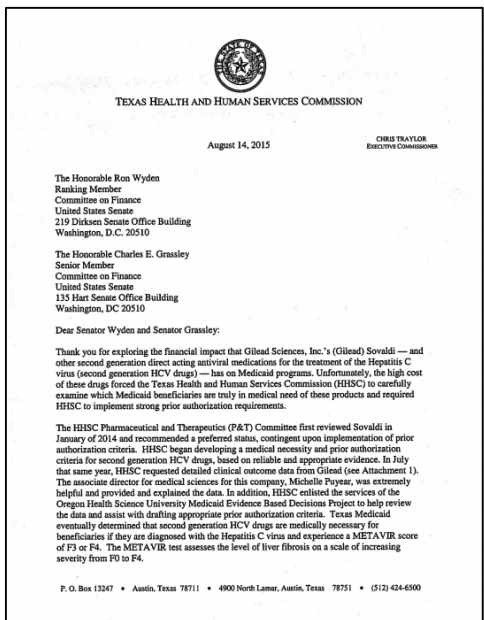


TEXAS HEALTH AND HUMAN SERVICES COMMISSION

CHRIS TRAYLOR
EXECUTIVE COMMISSIONER

August 14, 2015

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Charles E. Grassley
Senior Member
Committee on Finance
United States Senate
135 Hart Senate Office Building
Washington, DC 20510

Dear Senator Wyden and Senator Grassley:

Thank you for exploring the financial impact that Gilead Sciences, Inc.'s (Gilead) Sovaldi — and other second generation direct acting antiviral medications for the treatment of the Hepatitis C virus (second generation HCV drugs) — has on Medicaid programs. Unfortunately, the high cost of these drugs forced the Texas Health and Human Services Commission (HHSC) to carefully examine which Medicaid beneficiaries are truly in medical need of these products and required HHSC to implement strong prior authorization requirements.

The HHSC Pharmaceutical and Therapeutics (P&T) Committee first reviewed Sovaldi in January of 2014 and recommended a preferred status, contingent upon implementation of prior authorization criteria. HHSC began developing a medical necessity and prior authorization criteria for second generation HCV drugs, based on reliable and appropriate evidence. In July that same year, HHSC requested detailed clinical outcome data from Gilead (see Attachment 1). The associate director for medical sciences for this company, Michelle Puyear, was extremely helpful and provided and explained the data. In addition, HHSC enlisted the services of the Oregon Health Science University Medicaid Evidence Based Decisions Project to help review the data and assist with drafting appropriate prior authorization criteria. Texas Medicaid eventually determined that second generation HCV drugs are medically necessary for beneficiaries if they are diagnosed with the Hepatitis C virus and experience a METAVIR score of F3 or F4. The METAVIR test assesses the level of liver fibrosis on a scale of increasing severity from F0 to F4.

P. O. Box 13247 • Austin, Texas 78711 • 4900 North Lamar, Austin, Texas 78751 • (512) 424-6500

HCV in our Centennial Care Population

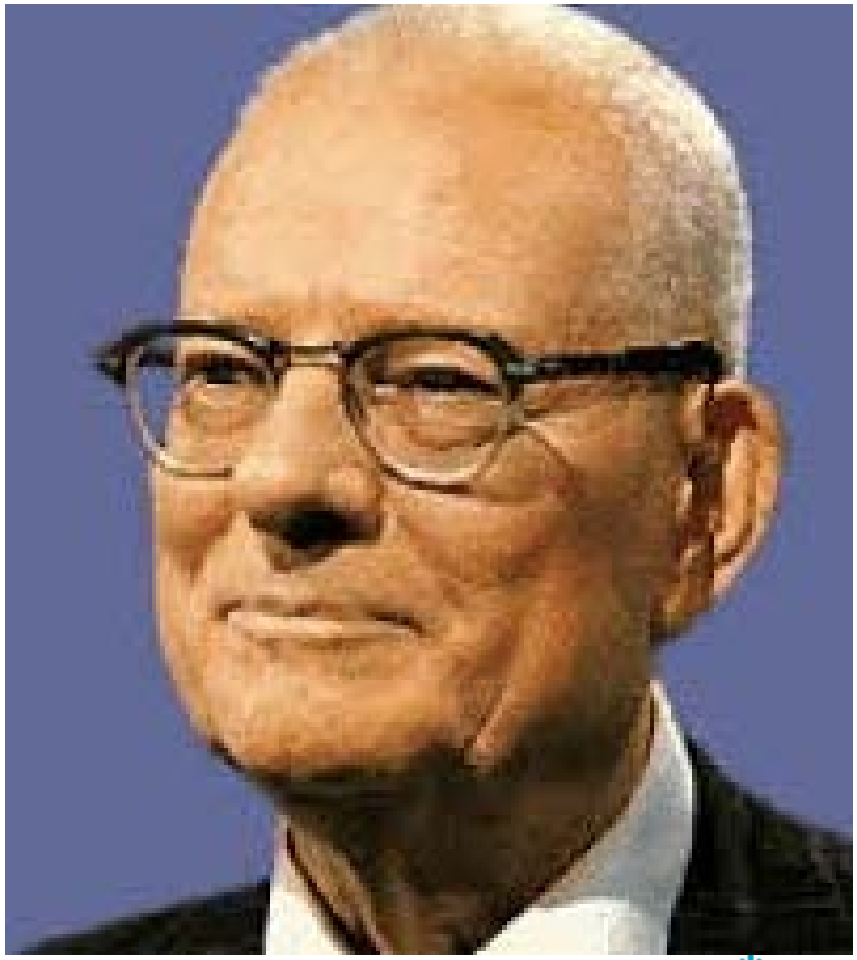
HUMAN SERVICES DEPARTMENT

HCV in Centennial Care: a Population Model

"All models are wrong. Some are useful."

W. Edwards Deming

(1900-1993), American engineer, professor, statistician, author, lecturer, management consultant



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The Importance of the Model

- The cost to treat all Centennial Care members with chronic HCV is likely > $1 billion
- Being over budget by even 100 courses of treatment in a single year = $10,000,000, a factor with equal impact to Health Plans, MAD/HSD, and New Mexico
- The budgetary problem is primarily short-term (5 years) while we treat the backlog of previously untreated HCV-positive individuals
- Once the backlog has been treated, the “run rate” expense may be in the $20 - $50 M per year range for New Mexico

HUMAN SERVICES DEPARTMENT

Key Model Conclusions

- NM HCV + individuals ≅ 38,000
- CC HCV + individuals ≅ 13,800
- CC *known* HCV + individuals = 6,918
- CC *known* HCV + individuals likely to get treatment (if no restrictions = 3,585)
  - F0 = 580
  - F1 = 1,255
  - F2 and greater = 1,721
- Target for 2016 = 1,750
  - Remaining 29 may be accounted for by extrahepatic HCV manifestations and other high risk groups

HUMAN SERVICES DEPARTMENT

Additional Calculations by Kimberly Page, PhD at UNM

Prevalence of HCV in New Mexico

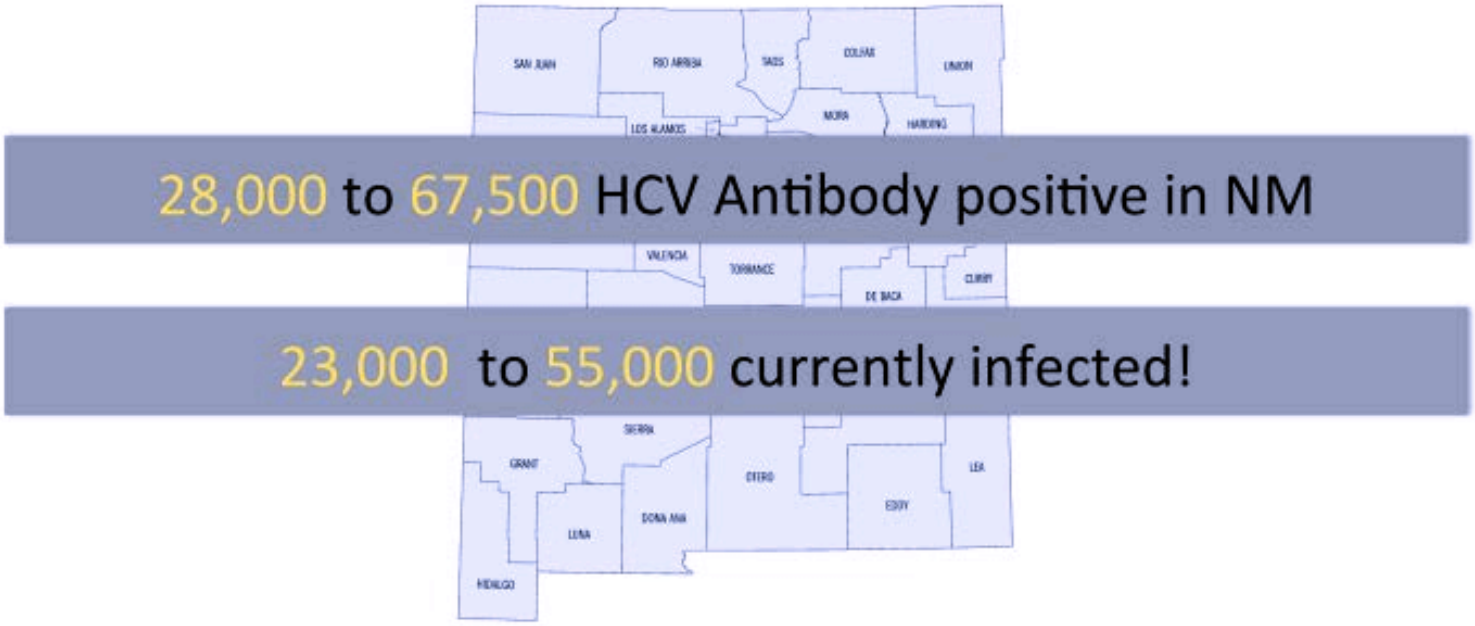
- NHANES (1% prevalence)
  - 20,856
- Populations not included in NHANES (2014):

Population	Estimated Size	Lower Estimate		Upper Estimate	
		%	Infected	%	Infected
Prison (incl. probation/parole)	25,336	23.0	5,827	41.1	10,413
Homeless	2,746	1.0	27	36.7	1,008
Hospitalized	2,198	1.0	21	17.0	361
Nursing homes	n/a	-	-	-	-
Active-duty military	n/a	-	-	-	-
Indian reservations	121,636	1.0	1,216	11.5	13,988
Total			**7,092**		**27,176**

HUMAN SERVICES DEPARTMENT

Additional Calculations by Kimberly Page, PhD at UNM

Prevalence of HCV in New Mexico



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HCV in our Centennial Care Population: Current Treatment

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New Mexico Data

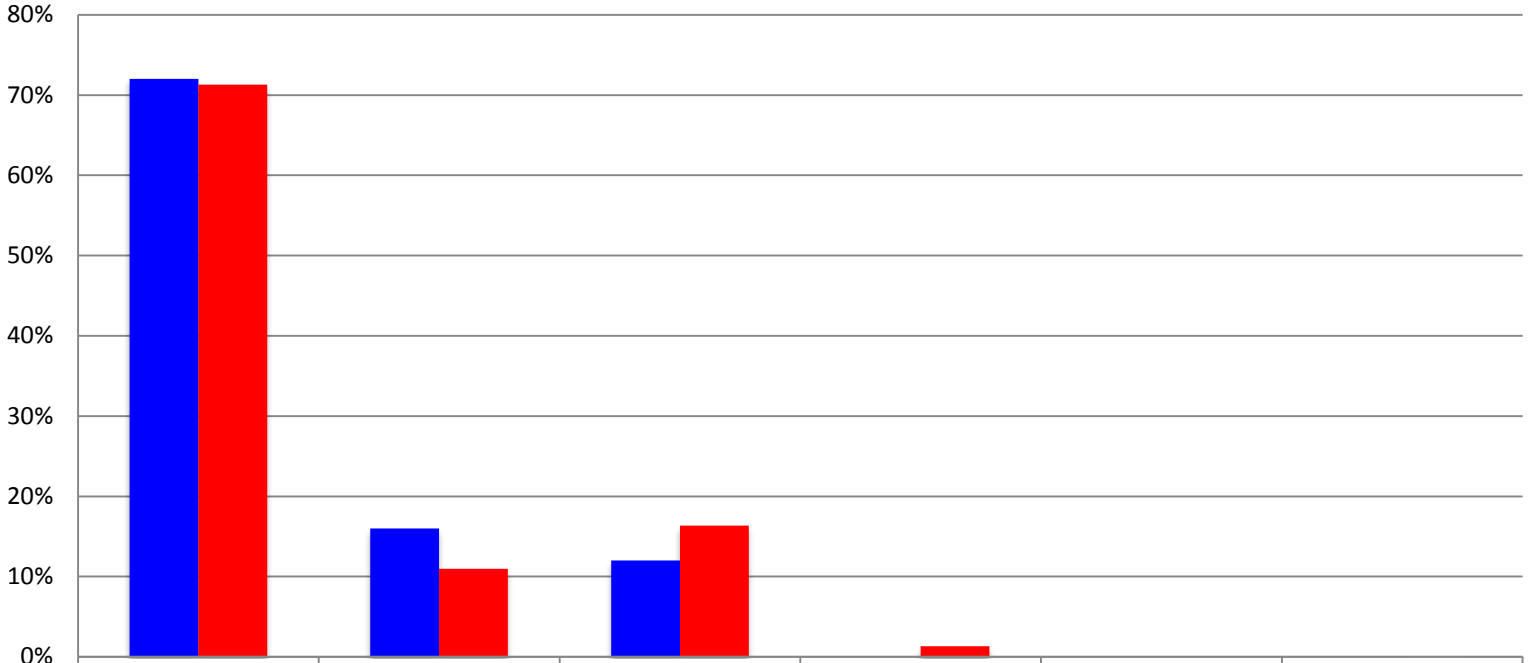
- The four Centennial Care health plans have been submitting data regarding all members for whom there was a request for HCV treatment in 2014-2016 YTD
- Health plans provided genotype for each patient, and a level of fibrosis when available
- Southwest Care Center also provided genotype data

HUMAN SERVICES DEPARTMENT

New Mexico Genotype Data

(through 10/31/2015)

Distribution of HCV Genotype
US (NHANES data) vs. New Mexico (MCO data 2014-2015 YTD)



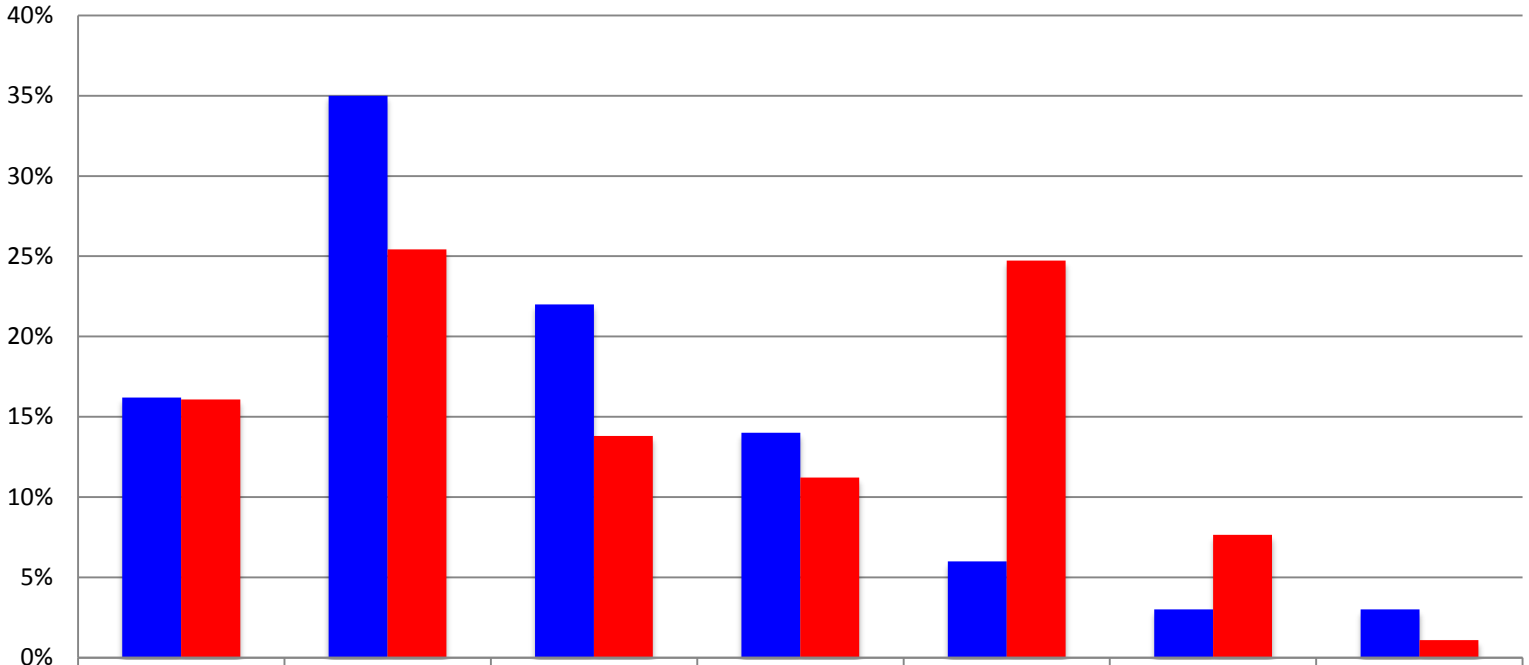
	1	2	3	4	5	6
US (NHANES)	72%	16%	12%	0%	0%	0%
NM (MCO data)	71%	11%	16%	1%	0%	0%

HUMAN SERVICES DEPARTMENT

New Mexico Fibrosis Stage Data

(through 10/31/2015)

Distribution of Fibrosis Stage
US (NHANES data) vs. New Mexico (MCO data 2014-2015 YTD)



	0	1	2	3	4	DC	HCC
US (NHANES)	16%	35%	22%	14%	6%	3%	3%
NM (MCO data)	16%	25%	14%	11%	25%	8%	1%

HUMAN SERVICES DEPARTMENT

Centennial Care's goal of treatment for hepatitis C is:

- *By 2020, to reduce morbidity and mortality by providing evidence-based treatment for all of our identifiable members with chronic hepatitis C infection, while being responsible fiscal stewards.*

HUMAN SERVICES
DEPARTMENT

Goals of Treatment for Hepatitis C

- ***Centennial Care:*** *By 2020, to reduce morbidity and mortality by providing evidence-based treatment for all of our identifiable members with chronic hepatitis C infection, while being responsible fiscal stewards.*
  - ***BCBS:*** *To use limited resources in a reasonable/responsible manner to successfully treat as many members as possible, focusing on those who will receive the greatest clinical benefit.*
  - ***Molina:*** *To have transparent, easily accessible, consistent, up to date and evidence-based criteria which will permit greater and more equitable access to hepatitis C drugs.*
  - ***PHP:*** To treat all clinically appropriate individuals with chronic Hepatitis C with evidence-based treatment protocols, prioritizing the patient's clinical status and financial resources.
  - ***UHC:*** *To treat the members most in need.*

HUMAN SERVICES DEPARTMENT

Best Practices from Centennial Care Health Plans

- BCBS – had been treating Fibrosis level 2 patients for all of 2015, (now treating all stages of HCV)
- Molina – Care Coordination role starts at the first receipt of treatment request
- PHP – through communication between finance and medical, opportunity to treat additional patients was identified and treatment guidelines expanded; 340B pricing
- UHC – communication regarding enhanced HCV screening to providers

HUMAN SERVICES DEPARTMENT

Action Plan for 2016

HUMAN SERVICES
DEPARTMENT

Action Plan Highlights for 2016

- Treatment criteria specified via a Letter of Direction on 12/1/2015, updated 7/27/2016
- Revised “checklist” and provider network education
- Expanded role of care coordination
- New data collection and staging requirements
- Expanded screening efforts
- Financial changes

HUMAN SERVICES DEPARTMENT

Treatment Criteria Explicitly Specified

- TREAT all patients over age 18, all genotypes, with F2 level or greater of fibrosis (or equivalent):
  - APRI score greater than 0.7 (use 40 for AST ULN), ***OR***
  - FIB-4 greater than 1.45, ***OR***
  - Transient elastography (Fibroscan®) score greater than or equal to 7.1 kPa, ***OR***
  - Liver biopsy confirming a METAVIR score F2 or greater, ***OR***
  - Imaging study that shows cirrhosis, ***OR***
  - Although not widely used in New Mexico, a FibroSure® score of greater than or equal to 0.49 is also consistent with F2 level fibrosis

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Why Not Treat Everyone Now?

- Budgetary constraints suggest that we will be more effective in being able to treat everyone by 2020 if we continue to prioritize those patients with significant fibrosis, **who are most likely to benefit from treatment**
- The references for the treatment of F0-F1 patients provided in the guidance from AASLD/ASIM *still* do not contain a single published article (there are two posters and two abstracts from 2015 conferences)

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Why Not Treat Everyone Now?

- These references do not allow any peer reviewed critique of experimental methodology that is so valued in the medical research community
- The Medical Assistance Division feels that it is important to have an evidence based approach to our decision making, particularly given the > $1 billion cost of treatment

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Treatment Criteria Specified

- TREAT all patients with extrahepatic manifestations of HCV infection:
  - type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g. vasculitis), or
  - kidney disease
    - proteinuria
    - nephrotic syndrome or
    - membranoproliferative glomerulonephritis
  - lymphoma

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Treatment Criteria Specified

- Specifically, TREAT those with decompensated cirrhosis and hepatocellular carcinoma unless requesting physician certifies that patient life expectancy is < 12 months
- No restriction of prescribing provider to specific subspecialties is allowed
- No restriction of treatment based on active alcohol or other drug use is allowed

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Treatment Criteria Specified

- TREAT Other High Risk Populations with Level A or B Evidence for Treatment
  - Pre- and post-liver transplant, or other solid organ transplant
  - HIV-1 co-infection
  - Type 2 diabetes mellitus (insulin resistant)
  - Debilitating fatigue impacting quality of life (e.g., secondary to extra-hepatic manifestations and/or liver disease)

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Treatment Criteria Specified

- Retreatment after failed all-oral therapy: same criteria as for treatment, with ECHO consultation

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Treatment Criteria To Be Revisited Retroactively

- Health plans were required to go back and offer reconsideration to all patients who meet the new criteria, but were denied using previous criteria prior to December 1, 2015

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Revised "Checklist" and Provider Network Education

- One page checklist to focus on most common scenarios; ask only for information that will influence decision
- Provider Network Education
  - Health plan visits to key (top 5 requesting) provider groups to explain new criteria and new checklist
  - Longer term efforts between MAD, health plans and ECHO to develop a strategy for provider education
  - Stronger connection with ECHO program for retreatment for those who do not respond to, or relapse with, all oral therapy

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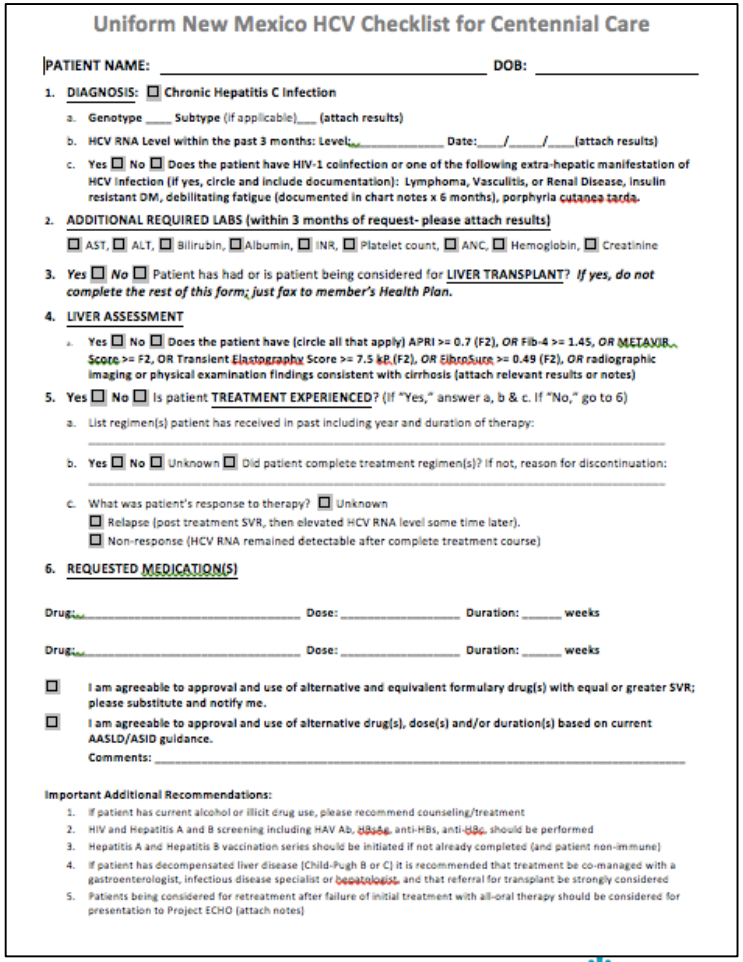
New Checklist

- Key changes:
  - F2 level of fibrosis defined for major testing modalities; only one test required
  - Lab work must be done in the past **3 months**
  - Interferon questions removed
  - Many (but not all) previous Checklist "requirements" now changed to recommendations to comply with CMS



Uniform New Mexico HCV Checklist for Centennial Care

PATIENT NAME: _____ DOB: _____

1. DIAGNOSIS: ☐ Chronic Hepatitis C Infection
   a. Genotype ____ Subtype (if applicable)____ (attach results)
   b. HCV RNA Level within the past 3 months: Level:_____ Date:____/____/____(attach results)
   c. Yes ☐ No ☐ Does the patient have HIV-1 coinfection or one of the following extra-hepatic manifestation of HCV infection (if yes, circle and include documentation): Lymphoma, Vasculitis, or Renal Disease, insulin resistant DM, debilitating fatigue (documented in chart notes x 6 months), porphyria cutanea tarda.
2. ADDITIONAL REQUIRED LABS (within 3 months of request- please attach results)
   ☐ AST, ☐ ALT, ☐ Bilirubin, ☐ Albumin, ☐ INR, ☐ Platelet count, ☐ ANC, ☐ Hemoglobin, ☐ Creatinine
3. *Yes* ☐ *No* ☐ Patient has had or is patient being considered for LIVER TRANSPLANT? *If yes, do not complete the rest of this form; just fax to member's Health Plan.*
4. LIVER ASSESSMENT
   a. Yes ☐ No ☐ Does the patient have (circle all that apply) APRI >= 0.7 (F2), *OR* Fib-4 >= 1.45, *OR* METAVIR Score >= F2, OR Transient Elastography Score >= 7.5 kP (F2), *OR* FibroSure >= 0.49 (F2), *OR* radiographic imaging or physical examination findings consistent with cirrhosis (attach relevant results or notes)
5. Yes ☐ No ☐ Is patient TREATMENT EXPERIENCED? (If "Yes," answer a, b & c. If "No," go to 6)
   a. List regimen(s) patient has received in past including year and duration of therapy:
      _____
   b. Yes ☐ No ☐ Unknown ☐ Did patient complete treatment regimen(s)? If not, reason for discontinuation:
      _____
   c. What was patient's response to therapy? ☐ Unknown
      ☐ Relapse (post treatment SVR, then elevated HCV RNA level some time later).
      ☐ Non-response (HCV RNA remained detectable after complete treatment course)
6. REQUESTED MEDICATION(S)

Drug:_____ Dose: _____ Duration: _____ weeks

Drug:_____ Dose: _____ Duration: _____ weeks

☐ I am agreeable to approval and use of alternative and equivalent formulary drug(s) with equal or greater SVR; please substitute and notify me.

☐ I am agreeable to approval and use of alternative drug(s), dose(s) and/or duration(s) based on current AASLD/ASID guidance.

Comments: _____

Important Additional Recommendations:

1. If patient has current alcohol or illicit drug use, please recommend counseling/treatment
2. HIV and Hepatitis A and B screening including HAV Ab, HBsAg, anti-HBs, anti-HBc, should be performed
3. Hepatitis A and Hepatitis B vaccination series should be initiated if not already completed (and patient non-immune)
4. If patient has decompensated liver disease (Child-Pugh B or C) it is recommended that treatment be co-managed with a gastroenterologist, infectious disease specialist or hepatologist, and that referral for transplant be strongly considered
5. Patients being considered for retreatment after failure of initial treatment with all-oral therapy should be considered for presentation to Project ECHO (attach notes)

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Expanded Role for Care Coordination

- Refer all patients to care coordination or community healthcare worker when request for medication received, per best practices within Centennial Care
  - Help to gather missing data for auth decision
  - Help verbally explain decision to patient
  - Help explain the need for medical follow up for patients denied care
  - Help with medication delivery and adherence, and follow up testing, for patients with care approved.
    - Some of these functions can also be met by health plan pharmacists, PBM and pharmaceutical company care management programs

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Data Collection Requirements

- "Stage" *all* patients as part of authorization process (whether approved or denied)
- Keep a sortable database so denied patients can be reconsidered when coverage guidelines change

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Quarterly reporting of members treated and prescription costs

- Plans submit quarterly reports of Prior Authorization data by genotype and fibrosis stage
- Plans are now provided their comparative data to all of Centennial Care after data submission complete
- If the number of Centennial Care HCV patients treated is significantly below target, MAD will re-evaluate treatment criteria

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Expanded Screening Efforts

- All plans required to develop screening program to include:
  - Publication of guidelines based on USPSTF (2013) or CDC (2013) or AASLD/ASID (2015)
  - Distribution to provider network
  - Distribution to members
- Considering member rewards for screening

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Align Financial Incentives

- Created a Delivery System Improvement Fund target to ensure that health plans are incentivized to provide treatment:
  - 2016: exceed 50% of treatment target
  - 2017: exceed ??% of treatment target
  - 2018: reach 100% of treatment target

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7/27/2016 LOD Update

- Clarify Delivery System Improvement Fund for Hep C related to *number of members* treated
- Request a further 20% reduction in cost per treatment course by 6/30/2017

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Quarterly MCO Meetings

- Review treatment data
- Review progress on DSIF treatment targets
- Discussion with ECHO experts
- Discuss benefit expansion timelines

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Fall 2016 Update:
So, what actually happened as a result?

- Significant increase in those treated in the last two months of 2015
- Near tripling of numbers treated on a monthly basis in the first 9 months of 2016
- 13% reduction in cost per treatment course

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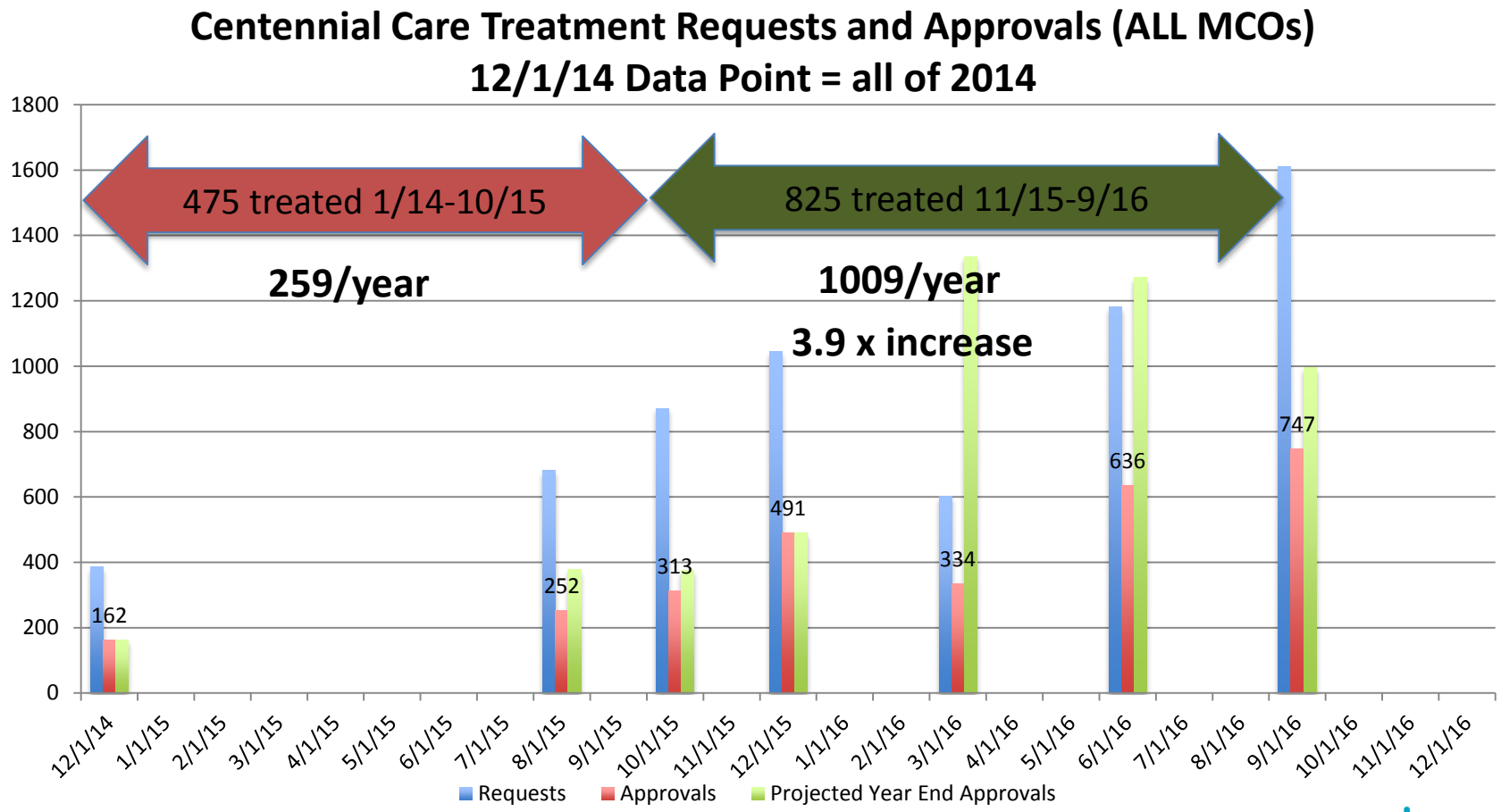
Dramatic Increase in Approval Rates



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What About Lawsuits in Other States?

- 5/27/2016: The **Washington** State Medicaid Program "is hereby ENJOINED from continuing to apply its February 25, 2015 HCV treatment policy, including its exclusion of all treatment based on fibrosis score, and is required to return to providing coverage for prescription medications to treat Hepatitis C virus ("HCV") without regard to fibrosis score, consistent with existing state and federal Medicaid requirements. The parties are hereby ORDERED to submit a joint status report to the Court sixty (60) days after the date of this order with an update as to the implementation of these changes."
- 5/27/2016: The **Florida** Agency for Health Care Administration announced Friday that it is taking corrective measures to ensure that state Medicaid recipients will have proper and timely access to Hepatitis C (HCV) treatment, including coverage of Direct-Acting Antiretrovirals. Florida was spurred to change course after the Florida Legal Services, Inc., Legal Aid Society of Palm Beach County, Inc., and the National Health LawProgram (NHeLP) discovered that the Florida health agency's policies were violating patients' rights pursuant to the Medicaid Act.
- 8/17/2016: **Colorado** board recommends expanded coverage for hepatitis C drug - ACLU threatens lawsuit over coverage policy

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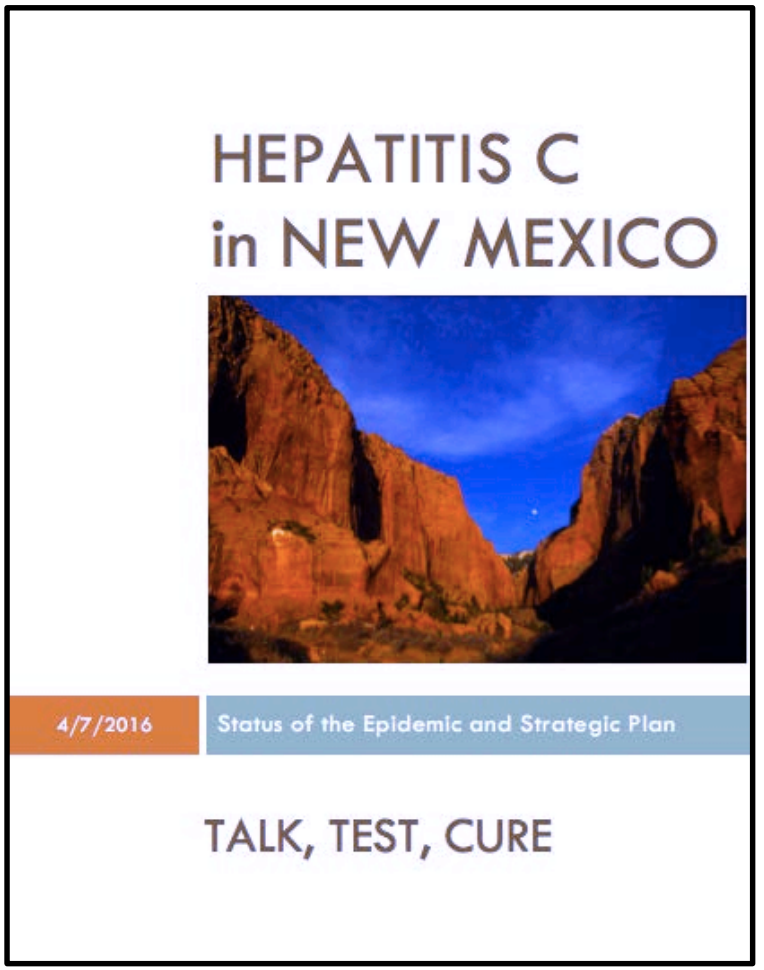
From the Hep C Coalition 2016 Strategic Plan

On December 12th 2015, **New Mexico's Medicaid program being very forward-thinking and strategic** in complying with and going beyond this guidance, to ensure broader access … To go beyond treating only the sickest of individuals infected with HCV (treating only those with a liver fibrosis score of F3 & F4), New Mexico's Medicaid program also increased treatment to include more recent infections with a liver fibrosis score of F2. **These changes to providing a cure will further ensure that all New Mexicans who are living with HCV will be treated within the next 5 years.**



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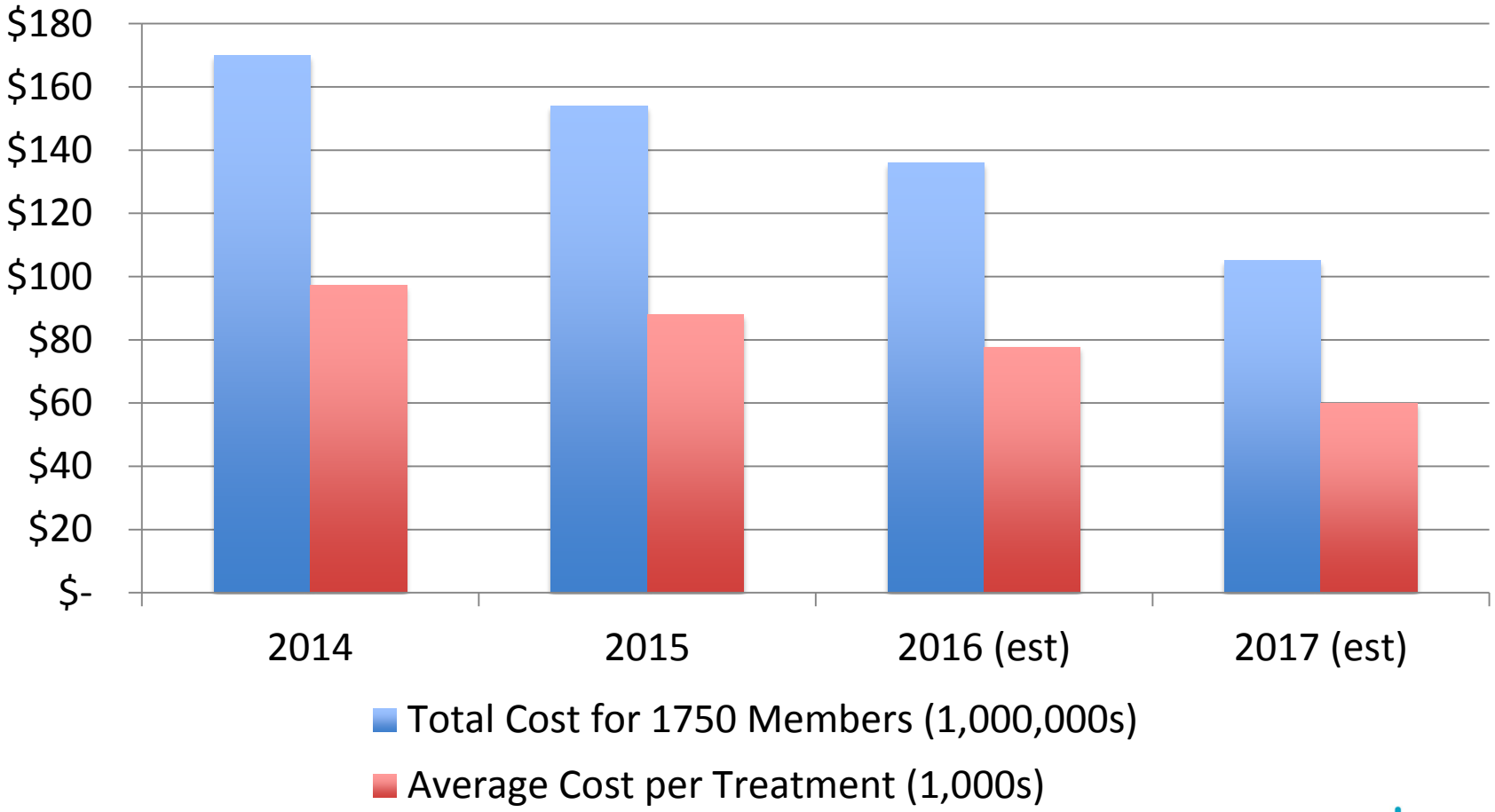
$500 Million of Good News for NM: Cost Per Treatment is Rapidly Declining



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Effect of Declining Prices

- Cost of treating 13,800 CC members at 2014 prices = $1.341 B
- Cost of treating 13,800 CC members at estimated 2017 prices = $828 M
- Savings 2017 vs 2014 = $513 M

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Additional Benefits

- What will the additional benefit be of moving from treating only the most advanced patients to treating *all appropriate patients* over the next 10 and 50 years?

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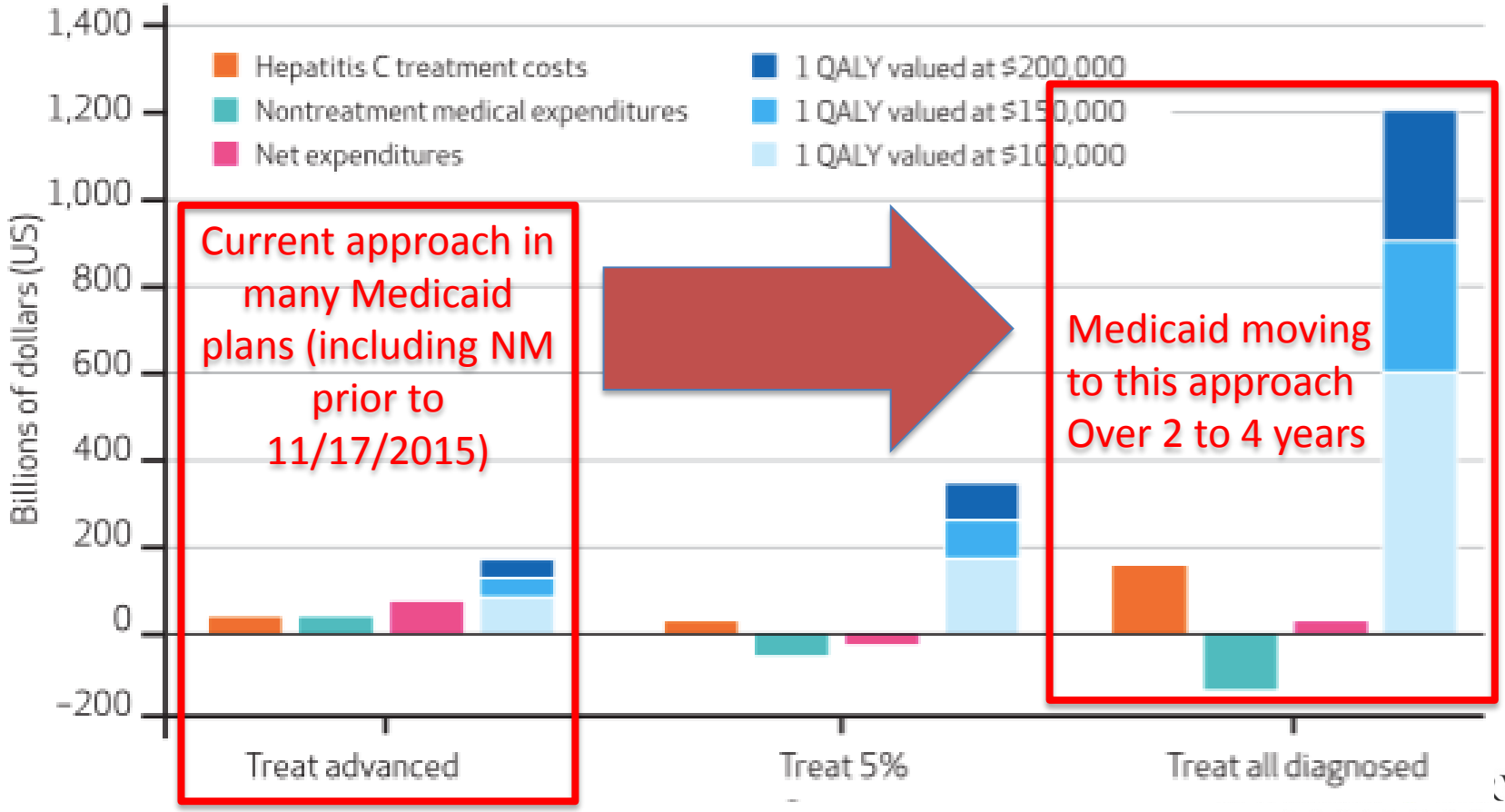
The Benefits of Earlier Treatment

Van Nuys K, Brookmeyer R, Chou JW, *et al.* **Broad Hepatitis C Treatment Scenarios Return Substantial Health Gains, But Capacity Is A Concern**. Health Affairs, 2015; 34 (10):1666-1674.

Cumulative Discounted Costs And Benefits Of Hepatitis C Treatment Strategies In A 50-Year Simulation Relative To Baseline, By Treatment Scenario



Projected 10-year **Centennial Care** Results

(in $ millions, QUALY = $150,000/year)

	Treat Sickest (2015)	Treat All (~2018)	Difference
Rx Cost	$(175)	$(500)	$(325)
Other Medical Costs	$(44)	$394	$438
QUALYs	$102	$570	$467
Total	$(117)	$112	$580

For the many assumptions related to QUALYs, Rx costs over time, treatment effectiveness, see Appendix, pages 14-19, in: Van Nuys K, Brookmeyer R, Chou JW, *et al.* **Broad Hepatitis C Treatment Scenarios Return Substantial Health Gains, But Capacity Is A Concern**. Health Affairs, 34, no.10 (2015):1666-1674.

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Centennial Care Hepatitis C Strategy Summary

- Goal to expand coverage to treat all chronic and active HCV patients by 2020
- Goal to provide evidence based coverage
  - Expand coverage to F1 fibrosis patients in 2017
  - Reduce cost per treatment course by 20% by 7/1/2017
  - Expand coverage to F0 fibrosis / all patients when financially feasible
- Continue to partner with Hepatitis C advocacy community

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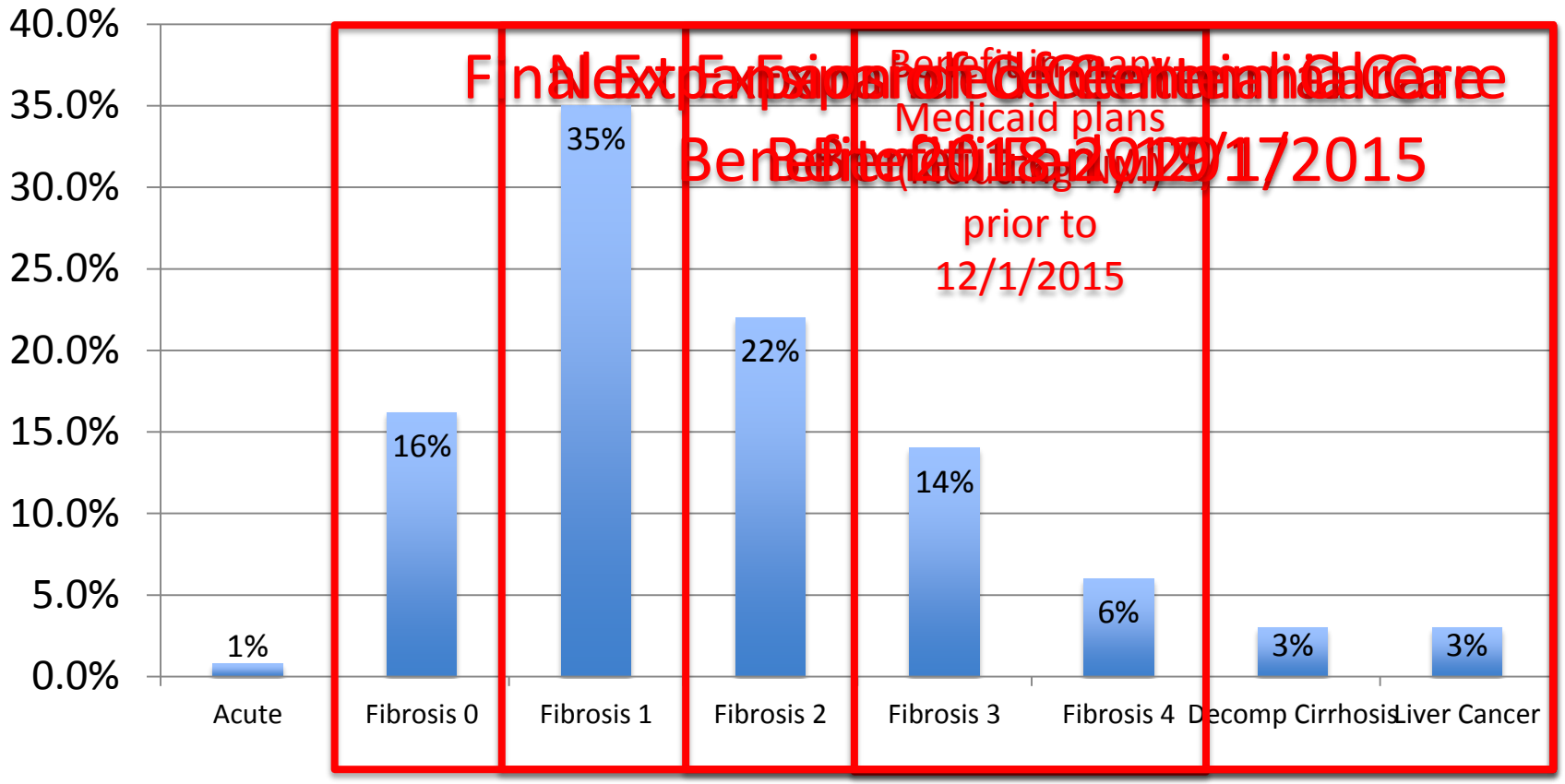
Summary of Centennial Care Benefit Expansion Timeline



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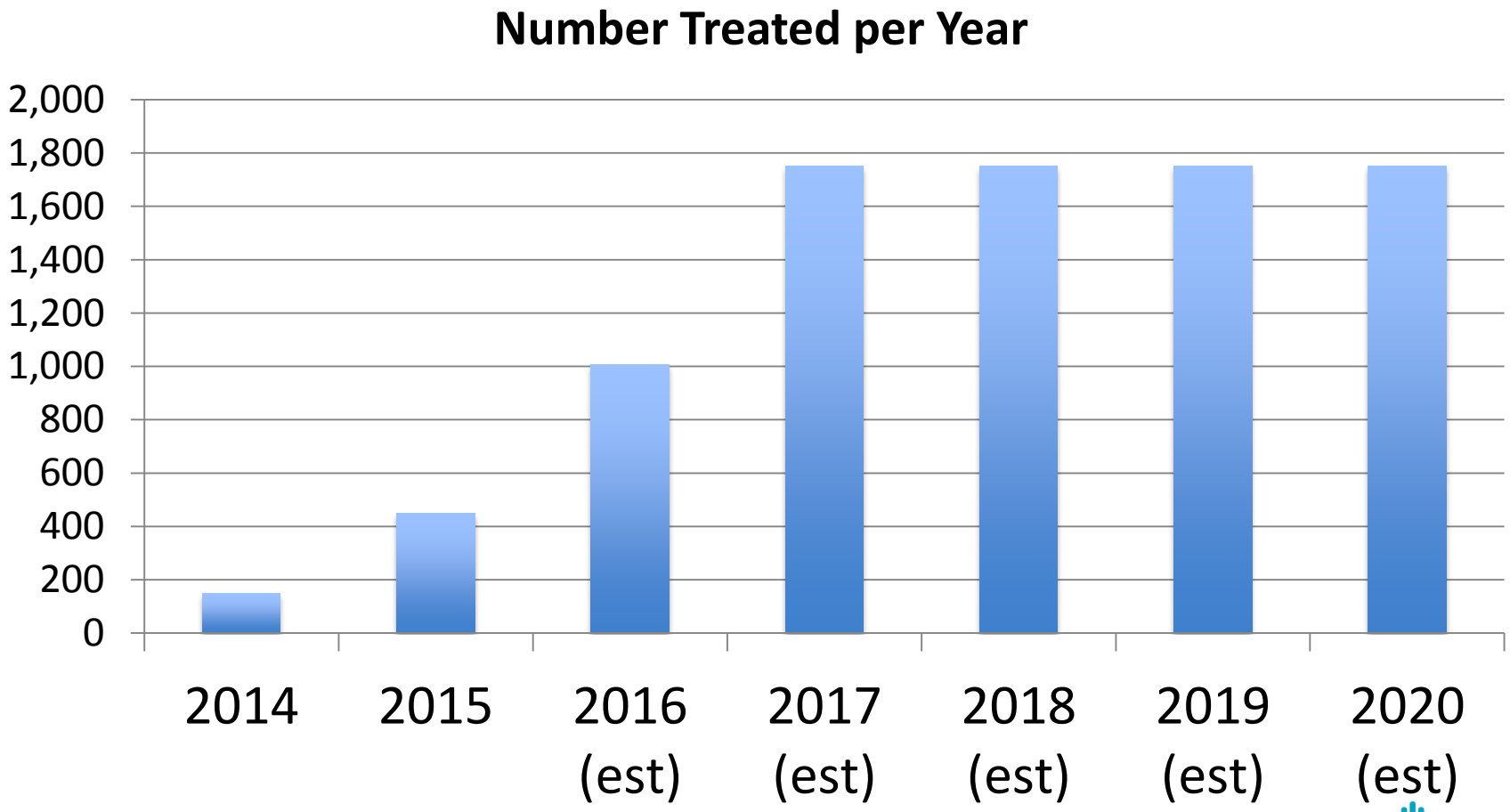
Key Challenge: Enhanced Screening



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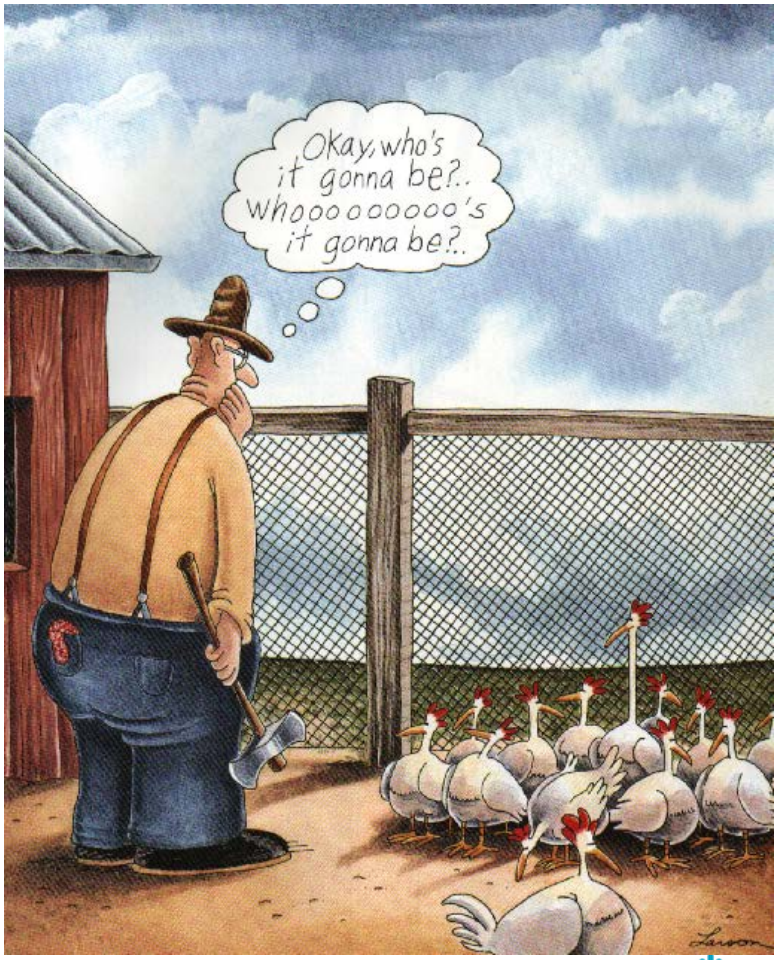
Two Important Obligations

- To treat all patients with active, chronic Hepatitis C infection
- To be faithful stewards of the state's limited financial resources



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Special Thanks to…

- Nancy Smith-Leslie, Director of the Medical Assistance Division
- Andrew Gans and Laine Snow from the DOH for their help with the population model
- The Hepatitis C Coalition for their collaborative development of a statewide strategy
- Karla Thornton, MD, with Project ECHO, for her help at every stage of this project
- All of the Health Plan Medical Directors and pharmacists who provided research articles and significant input and data to help us to make evidence based decisions
- This group, for supporting the efforts of Centennial Care with your time and talents.

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Questions? Comments?

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