

EXAMINING HEPATITIS C VIRUS TREATMENT ACCESS



A REVIEW OF SELECT STATE
MEDICAID FEE-FOR-SERVICE
AND MANAGED CARE PROGRAMS

The Epidemic Today

Hepatitis C (HCV) Incidence

- + CDC estimates 24,700 persons newly infected in 2012¹
- + Actual incidence is likely much higher. CDC gives a range for incident infections in 2012 of 19,600 – 84,400²
- + Epidemic of new infections among young people who inject drugs³

HCV Prevalence

- + CDC estimates 2.9 million people currently living with HCV in the US (number is likely much higher)⁴

HCV-related Deaths

- + CDC estimates at least 19,368 deaths from HCV in 2013 (likely much higher)
 - Beginning in 2007, HCV-related deaths exceeded that of HIV in the U.S. ⁵



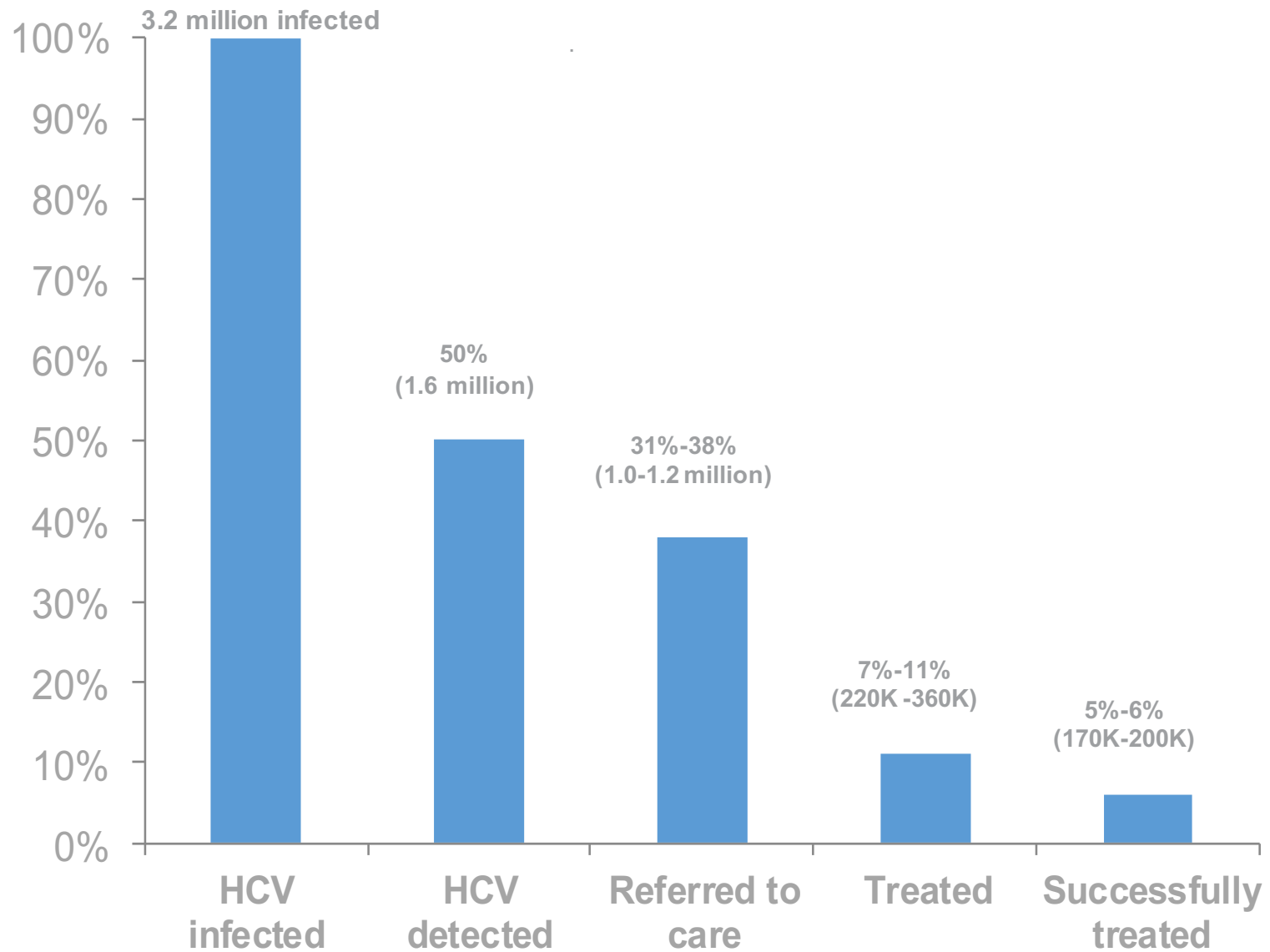
The Epidemic Today

The Urgency of HCV Treatment⁶

- + Severe liver complications expected to peak over the next decade
- + The cure is here
- + Individuals with >1 year life expectancy are treatment candidates
- + Treating active injection drug users and women of child-bearing age could result in significant transmission reduction
- + HCV is a communicable disease – treatment is prevention – ensuring we cure those populations means that we can dramatically decrease new infections

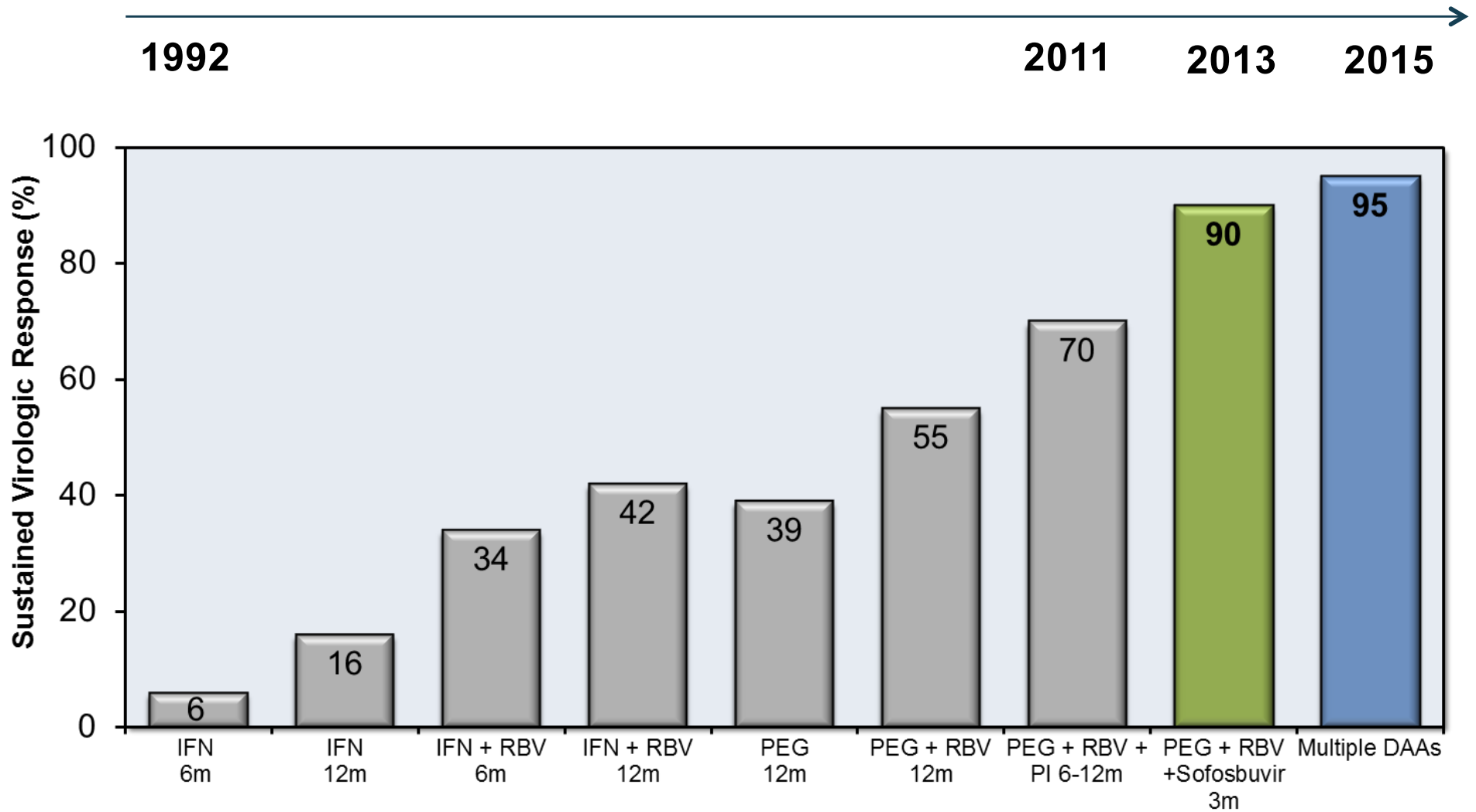


Where We're At – The Care Continuum⁷



Where We're At – Treatment⁸

Timeline



Hepatitis C Treatment Options 2015

Genotype	FDA Approved Treatments
1	Ledipasvir/sofosbuvir (Harvoni) or or Abbvie 3D regimen (Viekira pak) +/- ribavirin or Simeprevir (Olysio) combined with Sofosbuvir (Sovaldi)
2	Sofosbuvir (Sovaldi) + ribavirin x 12 weeks
3	Sofosbuvir (Sovaldi) + ribavirin x 24 weeks
Genotypes 4,5,6	Refer to AASLD/IDSA Guidelines ⁹



Medicaid Programs and Drug Formularies

State Medicaid Expansion

- + 29 states (including DC) adopted the Medicaid expansion; under discussion in 6 states; 16 states are not adopting¹⁰

Pharmacy and Therapeutics Committees

- + Providers, clinicians, and other partners make up the committee
- + Decide which drugs are included on formularies and what prior authorization criteria are attached to each drug

Fee-for-Service (FFS) vs. Managed Care Organizations (MCOs)

- + Most of the Medicaid population is shifting to MCOs¹¹
- + Some MCOs follow the state FFS guidelines, others set own criteria



Decisions to Limit Access to HCV Treatment

Limits on Access Based on Stage of Fibrosis

- + Limiting treatment to those with Metavir score of F3/F4

Restrictions Based on Substance Use

- + Period of abstinence from substance use

Prescriber Limitations

- + Prescription by, or in consultation with, a specialist



Other Restrictions

Additional Prior Authorization Criteria:

- + HIV co-infection limitation
- + “Once per lifetime” limitation
- + Genotype limitations
- + Previous history of treatment adherence required

New Insurer-Based Restrictions

- + Exclusivity agreements in place that limit patient/provider treatment option in exchange for increased discounts



Examining HCV Treatment Access Report¹²

10 State Profiles

- + Profiles give an overview of HCV in ten states
 - CO, FL, IL, LA, MA, NY, NC, OR, PA, RI
- + Examine accessibility of Sovaldi through Medicaid fee-for-service programs
- + In five select states look at restrictions in Medicaid managed care plans that can differ from fee-for-service programs
 - MA, NY, LA, PA, OR



Illinois Sovaldi Prior Authorization Criteria: Very Restrictive

Coverage

- + Non-preferred drug

Fibrosis

- + Metavir score of \geq F4

Substance Use

- + No evidence of substance abuse in past 12 months

Prescriber Limitations

- + If prescriber is not a specialist, required one-time written consultation within past 3 months



10 State Report Spotlight: Massachusetts

HCV Prevalence

- + Approximately 197,000 individuals living with HCV
- + Incidence of HCV among 15–25 year olds has doubled in past decade
- + 14% of individuals living with HIV are also co-infected with HCV
- + 407 HCV-related deaths in 2011
- + Medical case management of individuals infected with HCV

MassHealth

- + First state to expand Medicaid program in 2006
- + Most individuals are enrolled in one of five MCOs



MassHealth FFS Sovaldi Prior Authorization Criteria: Less Restrictive

Coverage

- + Preferred drug

Fibrosis

- + No restrictions (form inquires)

Substance Use

- + No restrictions (form inquires about current use)

Prescriber Limitations

- + No restrictions

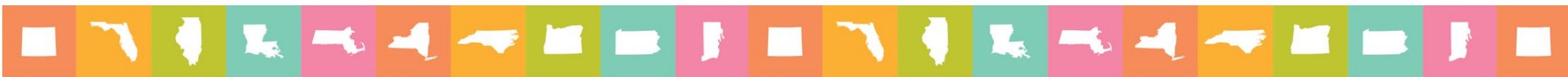
Additional Restrictions

- + No additional restrictions based on HIV Co-infection or previous adherence



MassHealth MCOs Sovaldi Prior Authorization Criteria:

	Boston Med. Ctr. Health Net Plan	Neighborhood Health Plan	Tufts Health Plan Network Health	Health New England
Fibrosis	F3-4	F3-4	F3-4	F4
Requirements Related to Substance Use	Not abused substances for 6 months	(For members with past/current issues) abstain from use for 6 months and participation in supportive care	No substance abuse within past 6 months OR receiving counseling services	(Known substance abusers) must have been referred to specialist; abstinence from substance abuse for 6 months; ongoing participation in treatment program; adequate psychosocial supports
Prescriber Limitations	Prescribed by or in consultation with specialist	Prescribed by or in consultation with specialist	Prescribed by specialist	Prescribed by specialist
HIV Co-Infection	Yes, with non-suppressable viral load or elevated MELD scores	Not without meeting additional requirements above	Not without meeting additional requirements above	Yes, if compliant with antiretroviral therapy as indicated by undetectable viral load
Additional Adherence Requirements	No history of nonadherence; enrollment in compliance monitoring program	Individual must demonstrate understanding of the proposed treatment, and display the ability to adhere to clinical appointments	"[M]ember has been assessed for potential nonadherence."	No ongoing non-adherence to previously scheduled appointments, meds or treatment; adherence counseling; willing to commit to monitoring



Massachusetts Qualified Health Plans – Prior Authorization Criteria¹³

	Fallon Health	Tufts	Harvard Pilgrim
Fibrosis	F3-4	F3-4	F3-4
Requirements Related to Substance Use	"[N]ot engaged in any habits that would negate the efficacy of the medications."	No illicit substance abuse within past 6 months OR receiving substance or alcohol abuse counselling services/seeing addiction specialist	None
Prescriber Limitations	Prescribed by specialist	Prescribed by specialist	Prescribed or supervised by specialist
HIV Co-Infection	None. Must meet other criteria as listed on this chart.	None. Must meet other criteria as listed on this chart.	None. Must meet other criteria as listed on this chart.
Additional Adherence Requirements	Must have been adherent to past therapies; must be prepared/motivated to start treatment. Application "require[s] a member's psychological and behavioral habits assessment in order to determine if the therapy is right for him/her."	"[M]ember has been assessed for potential nonadherence."	None



Next Steps – Reframe the Response

Shift the focus from cost to cure

- + Recognize payer concerns, but accurately assess the value of cure
- + With supplemental rebates the cure is now ~\$40,000 for Medicaid
- + Comparative effectiveness matters
 - + We paid over ~\$250,000 per HCV cure in interferon age
 - + In HIV, no cure and we pay ~\$10,000 per year for life for HAART
- + Pharmacy budget may increase but others will decrease
- + Medicaid is an entitlement program in part to grow to meet the demands created by innovation



Assess your health insurer's response to HCV coverage from a public health perspective

Insist that HCV be addressed as a serious public health issue

- + Screening and treatment have significant individual and public health benefits
- + The baby boomer generation is not the end of the epidemic, with increasing evidence of growing incidence in young people
- + Other serious diseases are not similarly treated (re: requiring disease progression or sobriety) and this undermines the public health response
- + Medicaid should adapt, not ignore, lessons learned from HIV treatment, where unrestricted access is the rule



Learn how health insurance grievance and appeal systems work

On a case-by-case basis we must fight for coverage, as we work to shift HCV treatment decision-making back to patients and their providers

- + Understanding grievance & appeals provisions¹⁴ promotes access to the cure
 - In Medicaid all applicants are entitled to “fair hearings” to dispute denials of treatment
 - In addition to the state fair hearing process, those in Medicaid managed care are entitled to internal appeals and grievance processes
 - In ACA private health insurance plans, all beneficiaries are entitled to internal appeals and the state’s division of insurance is charged with ensuring that plans are not engaging in discriminatory practices
- + Patients and providers must work together and persevere through prior authorization and other processes, insisting that access to the HCV cure is medically necessary



Employ systemic advocacy to support increased access to the HCV cure

Under the Medicaid Act all prescription drugs of a manufacturer who enters into “rebate agreements” must be covered, with only exceptions related to safety and clinical effectiveness¹⁵

- + The report demonstrates that coverage criteria for HCV are not about safety or effectiveness and are really about cost
- + Such restrictions are discriminatory !
- + While states have more discretion under prior authorization rules, even there courts have found access cannot be severely curtailed and the final say should remain with treatment providers
- + In some states state medical necessity laws require even fewer restrictions on access to life-saving medications
- + Systemic reforms should be pursued on both federal and state levels



Examples of Successful Efforts to Expand HCV Treatment Access

Washington¹⁶

- + All HCV services provided by Medicaid moving to fee-for-service model
- + Pending approval to expand eligibility to include a fibrosis score of F2
- + Pending approval to change requirement for people with history of IV drug use to prove abstinence for a 3-month period or be under the care of an addictions medicine specialist

Connecticut¹⁷

- + Expanded prescriber criteria to include HIV specialists

There is also some evidence that drug manufacturer and payer exclusivity deals are increasing access, with increased access tied to deeper discounts



Participate in coalition building and advocacy on federal and state levels

- + CHLPI and NVHR are working with federal partners to promote stronger HHS/CMS responses to expanding cure opportunities and reducing discriminatory practices
- + We are working with state partners to develop and activate state-level coalitions to fight restrictions
 - Plan is to develop replicable strategic messaging, litigation strategies, advocacy tools and materials
 - Trainings are planned to address stigma and to ensure strong leadership from those living with HCV in states
 - All materials and key learnings will be shared so they can be leveraged across other states

We need your help!



Sources

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- + ² *Statistics and Surveillance, Centers for Disease Control and Prevention, available at <http://www.cdc.gov/hepatitis/Statistics/> (last visited April 1, 2015).*
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- + ⁴ *Hepatitis C FAQs for the Public, Centers for Disease Control and Prevention, available at <http://www.cdc.gov/hepatitis/HCV/HCVfaq.htm> (last visited April 1, 2015); E. Chak, et al., Hepatitis C Virus Infection in the USA: an Estimate of True Prevalence, Liver Int. 31(8):1090.*
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- + ⁷ *Holmberg SD, et al. Hepatitis C in the United States. New Engl J Med. 2013;368:20:1859-1861.*
- + ⁸ *Michael Ninburg, Hepatitis Education Project*
- + ⁹ *AASLD/IDSA Guidelines: Recommendations for Testing, Managing and Treating Hepatitis C (revised Dec. 19, 2014), available at: www.hcvguidelines.org.*



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- + ¹¹*Managed Care*, Medicaid.gov, available at <http://medicaid.gov/medicaid-chip-program-information/by-topics/delivery-systems/managed-care/managed-care-site.html> (last visited April 1, 2015).
- + ¹²Center for Health Law and Policy Innovation of Harvard Law School Report - Examining Hepatitis C Virus Treatment Access: A Review of Select State Medicaid Fee-For-Service and Managed Care Programs
- + ¹³Center for Health Law and Policy Innovation of Harvard Law School, Matthew Kien-Meng Ly – Massachusetts Qualified Health Plans Prior Authorization Criteria
- + ¹⁴*A Guide to the Medicaid Appeals Process*, Kaiser Family Foundation (Mar. 29, 2012), available at <http://kff.org/medicaid/issue-brief/a-guide-to-the-medicaid-appeals-process/>.
- + ¹⁵*Medicaid Drug Rebate Program*, Medicaid.gov, available at <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program.html> (last visited April 1, 2015); 42 U.S.C. § 1396r–8
- + ¹⁶Michael Ninburg, Hepatitis Education Project
- + ¹⁷*Connecticut Medical Assistance Program Hepatitis C Prior Authorization (PA) Request Form – Sovaldi*, State of Connecticut Department of Social Services (Jan. 2015), available at <https://www.ctdssmap.com/CTPortal/PharmacyInformation/tabid/65/~Information/Get%20Download%20File/tabid/44//Default.aspx?Filename=Sovaldi%20PA%20Request%20Form.pdf&URI=Forms/Sovaldi%20PA%20Request%20Form.pdf>.

