

HCV and Health Law in U.S. Incarceration Settings



The HIV/HCV Co-Infection Watch is a publication of the Community Access National Network (CANN). It is a patient-centric informational portal serving three primary groups – Patients, Healthcare Providers, and AIDS Service Organizations.

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Law Overview

Constitutional Right to Treatment:

- Incarcerated are only population guaranteed the right to medical treatment under 8th Amendment protection from “...cruel and unusual punishment” (*Estelle v. Gamble*, 1976)

Estelle v. Gamble (1976):

- Established several precedents:
 - Established concept of “deliberate indifference” (Schoenly, n.d.b)
 - If inmates need medical attention, this cannot be denied
 - If care cannot be provided by onsite staff, adequate and timely access must be provided
 - If medical staff determine that treatment is needed and orders treatment or medication, it must be honored
 - Neither security staff, nor internal processes (bureaucracy) can hinder the required treatment
 - Treatment cannot be countermanded
 - Right to professional judgement - decisions should be made based on medical need, rather than on security need or convenience (Schoenly, n.d.a)

Deliberate Indifference:

1. Serious medical need
 - a. Diagnosed by physician as requiring treatment
 - b. The need is so obvious that even a lay person would know it needed treatment
2. Staff must know about serious need
3. Staff must intentionally and deliberately fail to provide required treatment for that need
4. Failure to treat caused inmate unneeded pain or suffering or similar harm

Estelle v. Gamble and Hepatitis C:

Incoming Prisoner Screening and Assessment

- Standard E-02 – Receiving Screening
 1. Medical Clearance
 - a. Should occur as soon as individual is admitted into facility
 - b. Quick inspection to determine emergent needs
 - c. Unlikely to catch HCV
 2. Structured Screening ASAP
 - a. Series of specific questions and standard patient intake protocol to determine existing patient needs
 - b. No concrete timeframe; should be completed all at once to ensure compliance
- Standard E-04 – Initial Health Assessment
 1. Full Population Assessment
 - a. Performed on 100% of inmates ASAP, but no later than seven days (prisons/juvenile facilities) or 14 days (jails)
 - b. Review of E-02 screening results
 - c. **REQUIRED** laboratory and/or diagnostic testing for communicable diseases
 - i. Testing for STDs required in all cases with one exception: facility may work with local health department to determine whether local prevalence rates warrant routine testing
 2. Individual Assessment When Clinically Indicated
 - a. Jails and Prisons Only
 - b. Many more requirements than first option
 - c. Facility must have on-site health staff coverage 24/7
 - d. Requires all inmates to have comprehensive receiving screening in addition to standard E-02 (National Commission on Correctional Health Care, 2011, 2016)

Federal Screening Guidance

“Testing for HCV infection is recommended for (a) all sentenced inmates, (b) all inmates with certain clinical conditions, and (c) all inmates who request testing” (Federal Bureau of Prisons, 2016)

Five-Step Process:

- 1. Test for HCV Infection with anti-HCV (HCV Ab) test** (see above)
- 2. Perform a baseline evaluation of inmates who are anti-HCV positive**
 - Targeted history and physical exam
 - Lab Tests – CBC, PT/INR, liver panel, serum creatinine and eGFR, HBsAg and HIV Ab, quantitative HCV RNA viral load with reflex testing for HCV genotype
- 3. Assess for hepatic cirrhosis/compensation and BOP priority criteria for treatment, if HCV RNA is detectable**
 - Assess for hepatic cirrhosis/compensation: Calculate APRI score if no obvious cirrhosis; Calculate CTP score if cirrhosis is known or suspected
 - Assess for BOP priority criteria for treatment of HCV
- 4. Perform a pretreatment assessment, if priority criteria for treatment are met**
 - Determine the most appropriate DAA regimen(s)
 - DAA regimen selection is based on HCV genotype, cirrhosis, compensation, and drug interactions
 - Refer to AASLD HCV guidelines, DHHS antiretroviral guidelines, and manufacturers’ prescribing information for specific drug interactions
 - Obtain pretreatment labs within 90 days of starting treatment
- 5. Monitor patient during and after treatment**
 - In accordance with Appendix 11, Hepatitis C Treatment Monitoring Schedule of the document *EVALUATION AND MANAGEMENT OF CHRONIC HEPATITIS C VIRUS (HCV) INFECTION (October 2016)*

Are Inmates Being Screened? – Maybe

Screening Criteria & Data:

- New HCV screening guidance introduced in October 2016 – adjustment period will occur (Federal BOP, 2016)
- Prisons likelier to screen than jails (Beckwith, 2015)
- Projections suggest newly adopted guidance could prevent 5,500 to 12,700 new infections caused by released inmates over 30 years (He, 2016)
- Federal BOP adopted an “Opt-Out” model of screening

Limitations of and Barriers to Data:

- Funding – Executive budget framework vs. Reality
- Data lag – time between research/polling, finalization, peer review, and publication phases
- Response from facilities – prisons likelier to response than jails (Beckwith)

Barriers to Screening:

- New screening guidance is cost-prohibitive in E-04 100% of population – Short-term expenditures > long-term health outcomes
- Cost of screening
- Jails generally have inmates for shorter periods than entire process allows
- Screening existing inmates costly, time consuming, and impractical
- Cost of required treatment likely outstrips entire corrections budgets

Avoid Treatment at All Costs (and All Costs of Treatment)

Screening and Treatment Avoidance:

- *Estelle v. Gamble* “deliberate indifference” leads some prison systems to avoid screening, and thus treatment costs
 - Tennessee Department of Correction (Boucher, 2016a):
 - Of 11,000 inmates admitted in 2015, only 901 were tested for HCV – 8.190% of incoming population
 - Of the 901 inmates tested, 424 tested positive for HCV – 47.059%
 - Existing TN Department of Correction (DOC) HCV Guidance recommends “Opt-In” method of screening – only if inmates have risk factors, meet certain clinical criteria, and/or request testing (Tennessee Department of Correction, 2016)
 - Lack of routine testing is key point in ACLU – TN case, *Graham, et al. v. Parker, et al.*
 - County Sheriff estimates almost all inmates in Claiborne County Jail are infected (Holloway, 2015)
 - Random testing of a few dozen inmates – 92% tested positive for HCV
 - Potential exposure via Injection Drug Use (IDU) and jailhouse tattoos
 - Nevada Department of Corrections (Botkin, 2017; Lundberg, 2016):
 - Nevada DOC Spokeswoman: “...Nevada state law requires testing for HIV/AIDS, but not hepatitis C” (Botkin)
 - 2015: state reports 593 inmates with HCV, only 2 of whom were being treated (0.34%) (Botkin)
 - March 2016: state reports 9 inmates being treated for HCV
 - State Prison v. Federal Policy v. Jail - Similar screening policies; State prisons largely guided by state statutes (Lundberg)
- Jails have easier time avoiding screening and delaying treatment:
 - Rarely have on-site medical professionals to screen
 - Shorter stays
 - Faster inmate turnover
 - Time to test, confirm, type, and treat may be longer than stay

Common Avoidance Techniques

1. Delaying testing

- a. Falls specifically outside established guidelines and timeframes set forth in E-04 standards
- b. Can be accomplished via administrative hurdles (e.g. – “We’re waiting to hear back”)
- c. More easily done in facilities that do not have qualified medical staff on-site 24/7

2. Using ostensible Opt-In screening model

- a. Prisons may ask inmates if they would like to be screened, rather than informing them that screening will occur, unless they decline
- b. Allows officials the ability to document that they “offered” testing, whether or not the patient understood what they were being asked or what options were available to them

3. Relying upon outdated statutes, laws, and regulations

- a. Only 11 prisons surveyed in 2012 conducted routine testing (Beckwith, 2015)
- b. State DOC officials fall back on “the law doesn’t require” argument, shifting blame to legislators
- c. Relying on local health department recommendations based on regional prevalence data

4. Needless and burdensome prerequisites for screening

- a. Requiring patients to undergo unneeded exams in order to access screening or medical services (Schoenmann & Morell, 2015)
- b. Waiting for visible effects of HCV to be apparent

5. Relying upon broad definitions of “treatment”

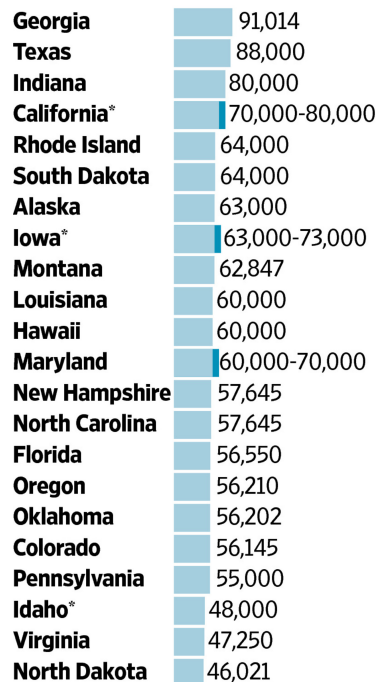
- a. Arguing (often in legislative and court proceedings) that “monitoring” patient progress via screening procedures qualifies as “treatment” under state and Federal requirements (Boucher, 2016b)
- b. Scheduling multiple medical appointments that only broadly address HCV-related issues

HCV Acknowledgement ≠ Treatment

Figure 1.

A Costly Cure

The per-patient price paid by state corrections departments for a 12-week course of Gilead Sciences Inc.'s hepatitis C drug Harvoni.



*Costs include Harvoni and other newer medications.

Source: state corrections departments

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Realities of Treatment and Costs at the State-Level:

- 2015: In forty-one states, 106,266 were known to have HCV – 10% of prison population (Beckman, 2016)
 - Only 949 (0.89%) of those inmates were receiving treatment (Beckman)
 - Costs for Sovaldi and Harvoni range from \$43,418-\$84,000 and \$44,421-\$94,500, respectively (Beckman)
- Treatment is expensive and costs per-patient vary wildly (Loftus & Fields, 2016a, 2016b)
 - Harvoni ranges from \$46,021 (North Dakota) to \$91,014 (Georgia) (Fig. 1.)
- Alaska DOC Chief Medical Officer admits to having an estimated 1,800 infected inmates out of 4,624 (38.93%); treating them all would cost nearly three times the state's \$40 million annual prison system health care budget (Loftus & Fields)
- Cost restrictions force state Departments of Correction to ration care (Gourlay, 2014)
- Tennessee DOC Commissioner requested \$4 million in additional funds to treat HCV (Boucher, 2016c); TN Governor Bill Haslam will propose \$2 million in his budget proposal (Boucher, 2017)

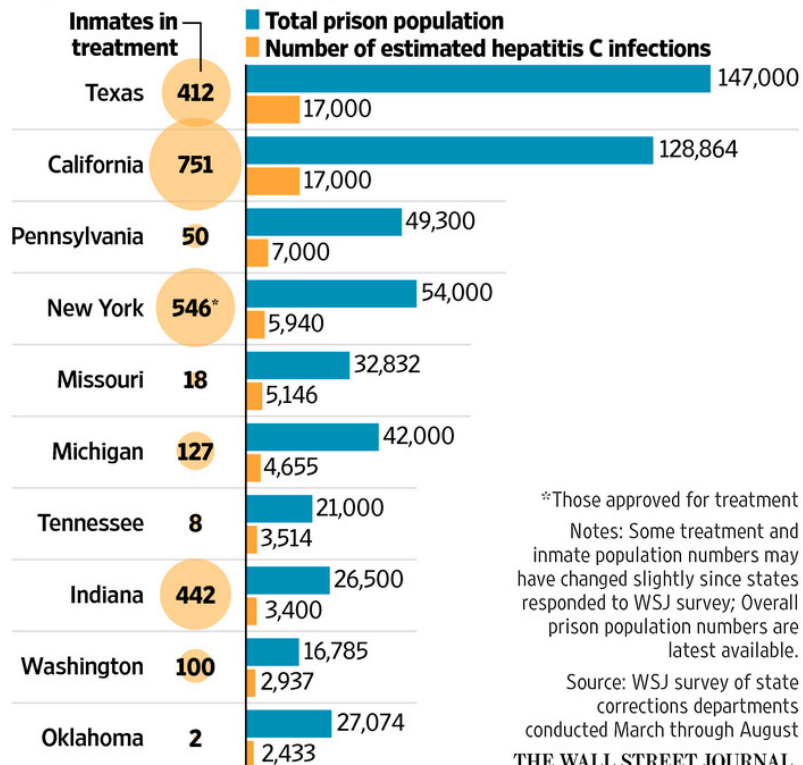
HCV Acknowledgement ≠ Treatment

Figure 2.

Many Infected, Few Treated

Newer drugs for hepatitis C have high cure rates—and high price tags to match. The cure/cost disconnect, doctors warn, is fueling a public-health crisis, especially in prisons. A Wall Street Journal survey of state corrections departments illustrates the problem.

Hepatitis C-infected prison populations by state



Realities of Treatment and Costs at the State-Level (Cont.):

- Despite acknowledging the number of inmates with HCV, percentages of those being treated represents a fraction (Loftus & Fields, 2016b, 2016c):
 - Texas – 2.42%; California – 4.41%; Pennsylvania – 0.71%; New York – 9.19%; Missouri – 0.35%; Michigan – 2.73%; Tennessee – 0.23%; Indiana – 13%; Washington (state) – 3.40%; Oklahoma – 0.08% (In order of listing on Figure 2) (Fig. 2.)

States with HCV-Related Lawsuits Involving Prisons (2007-2017)

Figure 3.

State	Year of Filing	Case Name	Type	Status
Alabama - AL				
	08/18/14	Black v. Alabama Department of Corrections, et al.	Civil Rights Action	Decided
	07/25/14	Braggs v. Dunn, et al.	Class-Action	In Trial
California - CA				
	07/08/08	Jackson, et al. v. Dezember, et al.	Class-Action	Dismissed
	10/10/08	Jackson v. Traquina, et al.	Civil Rights Action	Dismissed
Illinois - IL				
	09/02/09	Fox v. Barnes, et al.	Civil Rights Action	Settled
	09/29/08	Orr, et al. v. Elyea, et al.	Class-Action	
	06/17/13	Fox v. Barnes	Civil Rights Action	
Massachusetts - MA	06/10/15	Paszko, et al. v. O'Brien	Class-Action	Ongoing
Minnesota - MN	06/03/15	Ligons, et al. v. Minnesota Department of Corrections		
Missouri - MO	12/15/16	Postawko, et al. v. Missouri Department of Corrections	Class-Action	Ongoing
Pennsylvania - PA				
	01/28/13	Runkle v. Commonwealth of Pennsylvania, Department of Corrections, et al	Class-Action	Dismissed
	06/12/15	Chimenti, et al. v. Pennsylvania Department of Corrections, et al.	Class-Action	Discovery
	08/24/15	Abu-Jamal, et al. v. Kerestes, et al.	Class-Action	Ongoing
	01/03/17	Abu-Jamal v. Wetzal	Civil Rights Action	Ongoing
Tennessee - TN	07/25/16	Graham aka Stevenson & Davis v. Parker, et al.	Class-Action	Ongoing
Texas - TX	Initial 06/09/05	Trigo v. Texas Department of Criminal Justice - Institutional Division, et al.	Civil Rights Action	Dismissed
Virginia - VA	11/21/16	Reid v. Clarke, et al.	Civil Rights Action	Ongoing

State/Federal HCV-Related Lawsuits Involving Prisons (2007-2017)

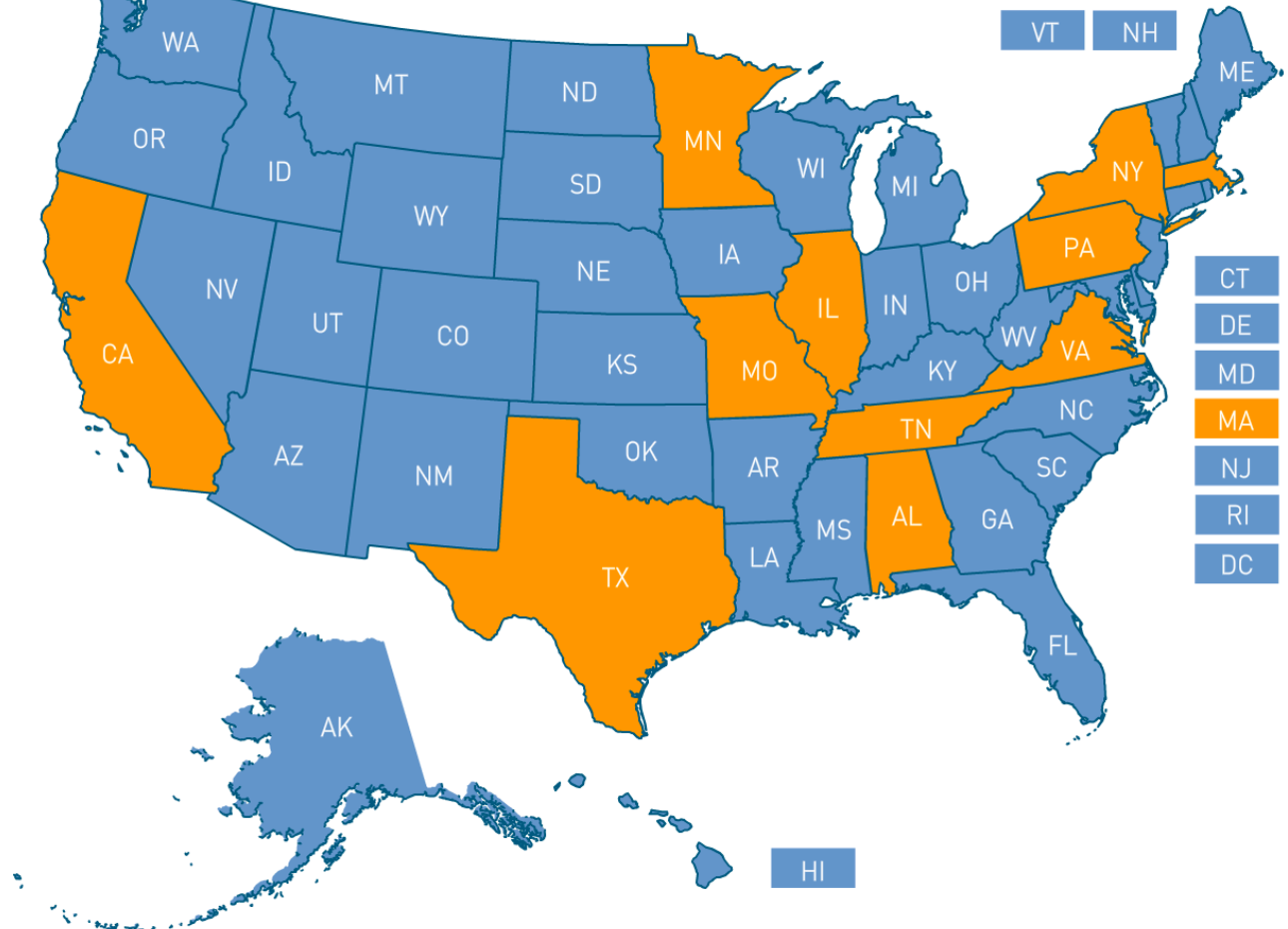
At least **18** Class-Action and Civil Rights Action lawsuits were filed in **11** states between 2007-2017. (This graphic may not represent every suit filed at all levels)

Figure 4.

Map Key:

Blue: No Lawsuits in Timeframe

Orange: Lawsuit(s) in Timeframe



n=18 total lawsuits

Recent Cases of Note

Graham, et al. v. Parker, et al. (Class-Action – Tennessee):

- Alleges that TN DOC “consistently and systematically denied” plaintiffs treatment
- March 2016: TDOC placed number of inmates testing positive at 3,487 (1 in 6)
 - Conceded number is likely far below actual infection rates due to lack of routine testing and inaccurate testing
 - As of May 2016, only 8 of the 3,487 HCV-infected inmates were receiving treatment with DAAs (0.23%)
- Alleges TDOC has “intentionally omitted [direct-acting anti-viral] treatment from [its HCV] Protocol and other policies to justify routine denial of treatment with these life-saving medications” (American Civil Liberties Union – Tennessee, 2016)

Postawko, et al. v. Missouri Department of Corrections, et al. (Class-Action – Missouri)

- Alleges that MDOC and its healthcare provider, Corizon, LLC, are “intentionally defying medical standards in refusing to adequately treat the thousand of inmates with Hepatitis C”
- Alleges that there are around 4,736 HCV-infected inmates in Missouri prisons, but only 5 are receiving adequate treatment (0.11%)
- Alleges that between 10-15% of the population in the custody of MDOC are infected with HCV, though the exact number of HCV-infected inmates in unknown due to a lack of routine testing (MacArthur Justice Center, 2016)

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Marcus J. Hopkins is a West Virginia native currently living in his familial hometown of Morgantown, WV. In 2005, Marcus was diagnosed HIV-positive.

After thirty years of involvement in the performing arts (vocal and instrumental music, color guard, and Drum Corps International), he currently spends most of his time dedicated to bringing attention, clarity, and comprehensive education to the world of Patient-Centric HIV and Hepatitis C research and reporting. Marcus presently serves as the Project Director for the HIV/HCV Co-Infection Watch, which is a publication of the Community Access National Network (CANN). He also blogs for CANN's "Hepatitis: Education, Advocacy & Leadership" (HEAL) coalition.

In his spare time, he's a video game-addicted, cat-loving insomniac who leaves audiobooks playing in the background at all times.



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