Recent Regulatory History of Addiction Treatment

Lessons and a Look to the Future; Where have we been? Where do we go from here?





"Those who cannot remember the past are condemned to repeat it."-George Santayana (1863-1952) Goals

-Historical developments as a framework for recurrent themes and tensions
-Understanding the recent evolution of the federal addiction treatment regulatory environment,
California regulation, and anticipated changes ahead
-How did we get where we are? Where do we go from here?





What we talk about when we talk about addiction

- Addiction as a pattern from substance <u>use</u>/behavior to <u>abuse</u> to <u>dependence</u>
- Etymology: Addictus (in Roman law) a person enslaved to repay debts
- ASAM: a primary, chronic disease of brain reward/motivation/memory/related circuitry
 - Manifesting biological, psychological, social and spiritual dysfunction
 - pathological pursuit of reward/relief, impairing behavioral control and craving, diminished recognition of significant problems with behaviors, interpersonal relationships, emotional response
 - risk of chronic cycles of relapse and remission
 - Progressive leading to death disability without treatment or engagement

NELSONHARDIMAN



3

Pre 1800s

- Addictive substances as a problem throughout human history
- Alcoholism/addiction as sin/moral failing
- Growing recognition of addiction as a problem with European colonial expansion, industrial revolution, and international trade
- No treatment or engagement that we would recognize focus on need for personal willpower





1800s

- Dr. Benjamin Rush ("Father of American Psychiatry") credited with pioneering therapeutic approach to alcoholism/addiction as medical disease; development of sober living homes
- 1858–NY State Inebriate Asylum in Binghamton, NY opens as the first U.S. treatment center (alcoholism, opium, morphine, cocaine, etc.) – growth of asyla as a 19th century model
- 1880s –First national brand in addiction treatment centers–
 Dr. Leslie Keeley's 120+ "Keeley Institute" opened as franchises
- 1880s+ Treatment of addiction with addictive substances (Sigmund Freud; Coca Cola)

Source: http://www.williamwhitepapers.com/pr/AddictionTreatment&RecoveryInAmerica.pdf





Early 1900s

- 1900s "Drunk tanks" for the poor and private sanitaria for the affluent
- 1914 Federal control of opiates via Harrison Narcotics Tax Act. 1919 U.S. Supreme Court decision *Webb v. U.S.* limits physician discretion: prohibits prescribing narcotics for maintenance of addicts. Rise of physician prosecution.
- 1920-1933 Prohibition as a legislative solution to evil of alcohol (18th Amendment; Volstead Act)
- 1920s Public health/police-run morphine maintenance clinics for the poor -eventually closed under federal pressure
- 1929 Narcotics Division as first federal agency leading to NIMH, ADAMHA, and eventually SAMHSA
- 1935 Beginning of Alcoholics Anonymous (AA)





Mid-1900s

- 1940s: National Committee for Education on Alcoholism (now NCADD) popularizes principles of addiction as a disease on a personal level and a public health crisis on a "macro" level. NCEA/NCADD advocates hospital-based detoxification, local alcohol
- information centers, local clinics for the diagnosis and treatment of alcoholism establishing "rest centers" for the long-term
- care of alcoholics
- (AA). 1940s media coverage speaks growth of 12-Step programs



1961: California Health and Welfare Agency





1960s and 1970s

- 1960s Some insurance coverage of alcoholism treatment begins; conflict over peer vs mental health professional models
- 1967 AMA acknowledges alcoholism as a disease
- 1970 Comprehensive Drug Abuse Prevention and Control Act of 1970—establishes Controlled Substance Schedules (I-V)
- 1972 Joint Commission begins to accredit addiction treatment programs
- 1972 FDA approves Methadone for heroin treatment
- 1973 DEA created within Department of Justice





1978: California Department of Alcohol and Drug Programs (ADP) created

Governor Brown folds
Office of Alcoholism into



California Department of Health's Division of Substance Abuse transfers responsibilities to



Department of Alcohol and Drug Programs (within Cal. Dept of Health and Human Services)





1973: Residential care ("community care") facilities established as distinct category from Healthcare Facilities

1978: Department of Social Services established within the Cal. Health and Welfare Agency along with the Departments of Health Services, Mental Health, Developmental Services, Alcohol and Drug Programs, and the Office of Statewide Health Planning and Development.



1980s and 1990s

- War on Drugs Resumes
- Managed Care cuts insurance coverage for inpatient and residential addiction treatment; driving outpatient and sober living growth
- 1988/1990 Inclusion of recovery from addiction as a protected class of disability in Fair Housing Act (1988 Amendment) and Americans with Disabilities Act (1990) for housing, employment
- 1992 Substance Abuse and Mental Health Services Administration (SAMHSA) and Center for Substance Abuse Treatment (CSAT) formed as part of HHS to increase availability of effective treatment and recovery services (1998 initial funding of states and community-based groups via block grants)
- 1993 HillaryCare proposes national substance use disorder insurance coverage benefit
- 1995 FDA approves naltrexone to treat alcoholism





2000: Drug Addiction Treatment Act (DATA)

- Permitted MDs with qualifications to treat opioid addiction with FDA-approved Schedule III, IV, and V narcotic medications
 - -permits prescribing and dispensing by waive MDs in treatment settings other than the traditional Narcotic Treatment Program ("methadone clinic") settings.
- At the time, only referred to buprenorphine (Methadone requires clinic)





2007: DHS Splits into 2 agencies





Department of Health

Care Services (DHCS)

Medi-Cal Program
Medi-Cal Fraud Prevention Bureau
State Controller's Office
Drug Medi-Cal Organized Delivery System



California Department of Public Health (CDPH)

Licensing of hospitals (including CDRHs), labs, home health agencies, hospices, CLHFs





14

2013: ADP Ceases to Exist

DHCS SUD Compliance Division takes over licensing, certifying, monitoring, and complaint investigation for DUI Programs, Narcotic Treatment Programs, outpatient and residential drug and alcohol treatment providers, certified Alcohol and Other Drug counselors.



Why DHCS?
Existing
Drug Medi-Cal
Program
oversight



Department of Health Care Services (DHCS) Substance Use Disorder (SUD) Compliance Division





2016: Comprehensive Addiction and Recovery Act (CARA)

- 2016 Comprehensive Addiction and Recovery Act (CARA)
 - \$80 million in funding for prevention, treatment, and recovery
 - Evidence-based opioid and heroin treatment and interventions programs
 - Improved prescription drug monitoring programs to help states monitor and track prescription drug diversion
 - Expand prevention and educational efforts—particularly aimed at teens, parents and other caretakers, and aging populations—to prevent the abuse of opioids and heroin and to promote treatment and recovery
 - Expand and develop community-based recovery services in communities across the country
 - Expand the availability of naloxone to law enforcement agencies and other first responders to help in the reversal of overdoses to save lives
 - Expand resources to identify and treat incarcerated individuals suffering from addiction disorders promptly by collaborating with criminal justice stakeholders and by providing evidence-based treatment
 - Expand disposal sites for unwanted prescription medications to keep them out of the hands of our children and adolescents





Parity and the ACA

- 2008 Mental Health Parity and Addiction Equity
 Act of 2008 prohibits financial requirements and
 treatment limitations for mental health and
 substance abuse benefits in group health plans
 from being more restrictive than those placed on
 medical and surgical benefits.
- 2010 Affordable Care Act required inclusion of mental health and substance use disorder (SUD) treatment services as part of the minimum essential coverage





Today: Awareness of addiction as an undertreated U.S. health crisis

- 46 million Americans with a mental health disorder
- 24 million Americans with alcohol or drug disorder
- 60-80 million Americans at risk or alcohol and drug problem (SAMHSA)





Takeaways: Where do we go from here?

- Evolving awareness of addiction as a public health crisis and a medical (rather than moral) condition
- Ongoing struggle to understand and develop an effective treatment model
- Access to care differentiated between "high-end" cash-pay for those with money and "low-end" public funded resource for the poor
- Competing ideas of clinician-led versus recovery community-led
- Insurance reimbursement as a driver of retrenchment, growth, and treatment setting
- Siloed regulatory categories continuing to change—higher degree of state-to-state variation in agencies and requirements than other healthcare services





An evolving understanding of where addiction treatment and substance use disorders fit in the broader healthcare context

Related but distinct from Mental
Health -focusing on a person's
condition with regard to their
psychological and emotional
well-being

Encompassed in **Behavioral Health** —all human behavior that is actionable- not merely promoting well-being by preventing or intervening in mental illness but also preventing or intervening in addictive disorders and a broader range of behavioral issues

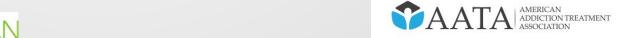




An evolving treatment model

Social model

Medical





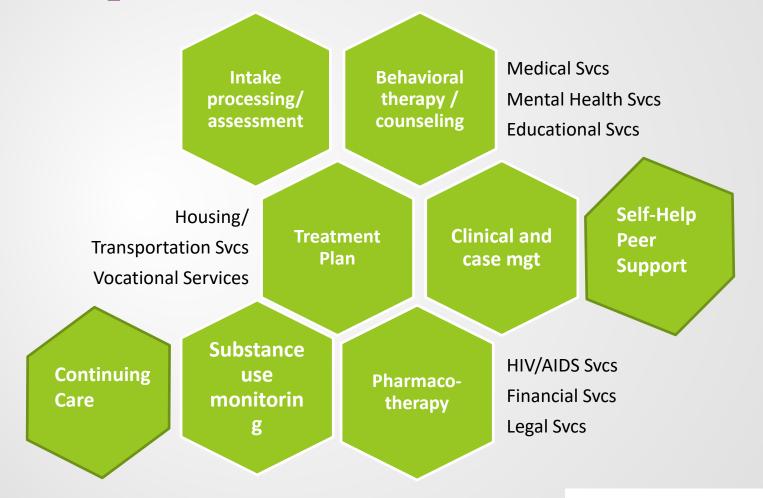
Shifting to Evidence-Based Practice

- Institute of Medicine (2001)
 - (1) "Best research evidence-the support of clinically relevant research, especially that which is patients centered",
 - (2) "Clinician expertise-the ability use clinical skills and past experience to identify treat the individual client"
 - (3) "Patient values-the integration into treatment planning of the preferences, concerns and expectations that each client brings to the clinical encounter".





An evolving view of the components of treatment







An evolving reimbursement model

From a system with the extremes of cash-pay and Medicaid funding To an insurance benefit mandated by the Affordable Care Act and a Parity prohibition on insurer discrimination





An evolving regulatory system?

From a "siloed" drug and alcohol licensing category

To a more integrated relationship with other healthcare and residential care models





Questions?





Harry J. Nelson: hnelson@nelsonhardiman.com

(310) 203-2800 www.nelsonhardiman.com www.addiction-tx.com