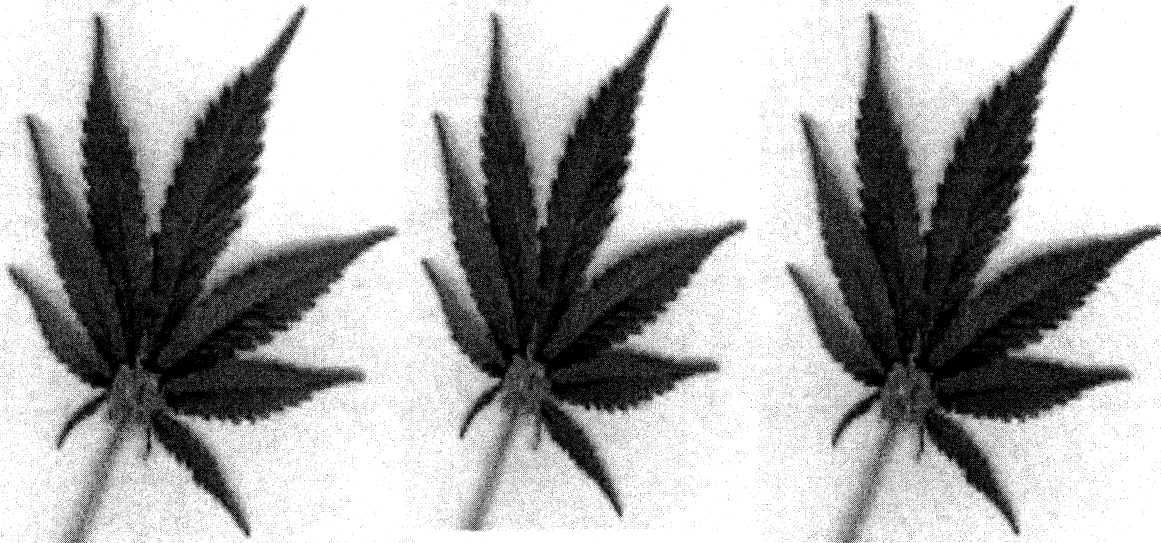


THE LEGALIZATION OF MARIJUANA: PROMOTION OF PATIENT SAFETY



Doris C. Gundersen MD

Medical Director

Colorado Physician Health Program

President

Federation of State Physician Health Programs

Disclosure to Audience

No one involved in the planning or presentation of this activity has any relevant financial relationships with a commercial interest to disclose

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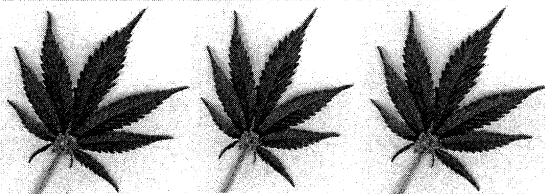
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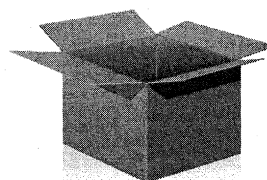
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Speaker Disclosure Statement

NOTHING TO DISCLOSE



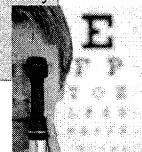
Educational Objectives

1. The Legalization of Marijuana: Colorado's Story
2. Become familiar with how CPHP approached policy development in an uncharted area of medicine and the law
3. Learn how PHPs and Regulatory Agencies can collaborate on issues pertaining to public safety as well as physician health

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1975 Compassionate Use Act

- Glaucoma - #1 cause of blindness
- 1992 - American Academy of Ophthalmology's Committee on Drugs - no scientific verifiable evidence that the use of marijuana is safe and effective in the treatment of glaucoma
- 1997 - NEI - no studies have demonstrated that marijuana can safely and effectively lower IOP any more than a variety of drugs on the market



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Glaucoma

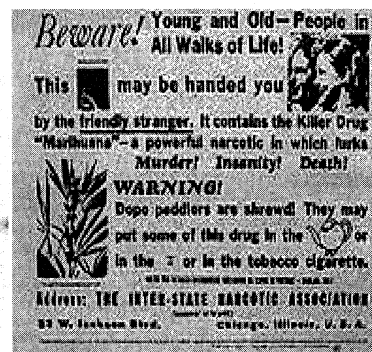
- 1999 - Institute of Medicine - although IOP can be reduced by using marijuana, the effect is too short lived and requires too high doses.
- There are too many side effects to recommend lifelong use in the treatment of glaucoma
- Average patient would have to smoke 10-12 "joints" per 24 hours to maintain low IOP through out the day



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CMS v. CPS



Efficacy and Safety Passionately Debated

"Rocky Mountain High" Colorado

November 2000

Coloradoans passed Amendment 20:

A small enterprise was envisioned

Colorado Department of Public Health and Environment was tasked with implementing and administering the Medical Marijuana Registry program

March 2001

Colorado Board of Health approved rules and regulations

June 2001

MMJ Registry began accepting applications for Registry Identification Cards.



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Rules and Regulations

- ☐ "Patient will be deemed to have established an affirmative defense to such allegation" (possession of marijuana) where:
- ☐ Patient was previously diagnosed by a physician as having a debilitating medical condition
- ☐ Patient was advised by his or her physician, in the context of a bona fide physician-patient relationship, that the patient might benefit from the medical use of marijuana in connection with a debilitating medical condition

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The Flood Gates Opened

- ☐ February 2009
 - Obama administration indicated that Medical Marijuana prosecution would have low priority
- ☐ October 2009
 - Obama administration will not seek to arrest medical marijuana users and suppliers as long as they conform to state laws
- ☐ State rule makers did not limit caregivers
- ☐ Applications increased dramatically
 - September 2009 - 3,523 applications received/month
 - December 2009 - 10,585 applications received/month
 - July 31, 2011 - 127,816 citizens in possession of cards



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The Passage of Amendment 20

Storefront "Medical" Marijuana dispensaries sprouted like weeds! (Pun intended)



"There are more medical marijuana dispensaries in Denver than Starbucks and liquor stores combined"

The Denver Post



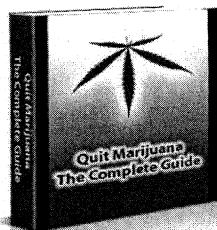
MMJ - A Recession Proof Industry

- ☐ Marijuana Growers
- ☐ Caregivers
- ☐ Legal Counsel
- ☐ Doctors making recommendations (\$\$\$\$)
- ☐ Grow Lights
- ☐ Vaporizers
- ☐ Pipes
- ☐ Edibles
- ☐ Advertising (Westword has gone "green")
- ☐ Festivals
- ☐ Delivery Services
- ☐ Armored Trucks



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MMJ – A Recession Proof Industry (detox services emerging)



Quit Marijuana The Complete Guide

Debilitating Conditions Defined

- ❑ Cachexia
- ❑ Severe Pain
- ❑ Cancer
- ❑ HIV/AIDs
- ❑ Seizures
- ❑ Persistent Muscle Spasms
- ❑ Severe nausea
- ❑ Glaucoma
- ❑ Any other medical condition approved by the state health agency (*none so far*)



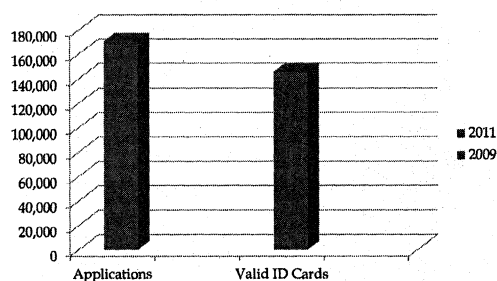
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Lobbying for New Conditions

❑ Unsuccessful so far:

- | | |
|-----------------------|----------------------|
| ▪ Asthma | MRSA |
| ▪ Atherosclerosis | Opioid Dependence |
| ▪ Bipolar Disorder | PTSD |
| ▪ Crohn's Disease | RA |
| ▪ Diabetes Mellitus | Diabetic Retinopathy |
| ▪ Anxiety Disorders | Hepatitis C |
| ▪ Depression | Hypertension |
| ▪ Tourette's Disorder | |

Exponential Growth



Demographic Summary

- ❑ 67% card carriers are male
- ❑ 41 years is the average age
- ❑ 60% card carriers concentrated in metro Denver
- ❑ 800 "prescribing" physicians



Conditions (April 2014)

- | | |
|-----------------|-----|
| ❑ Cachexia | 1% |
| ❑ Cancer | 3% |
| ❑ Glaucoma | 1% |
| ❑ HIV/AIDS | 1% |
| ❑ Muscle spasms | 13% |
| ❑ Seizures | 2% |
| ❑ Severe pain | 94% |
| ❑ Severe nausea | 10% |



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Either Colorado experienced an epidemic of severe pain in youthful males or.....

Amendment 20 was exploited by recreational users and financial opportunists



Physician MMJ Recommendations

- ▣ In the fall of 2009 @ 900 doctors had written approval letters (7% of licensed MDs)
- ▣ 15 doctors – 72% of recommendations
 - 5 of these 15 doctors have had disciplinary histories
- ▣ 5 doctors – 50 % of recommendations
- ▣ One doctor signed 3,500 certificates in a two day period (Making a mockery of responsible medicine)

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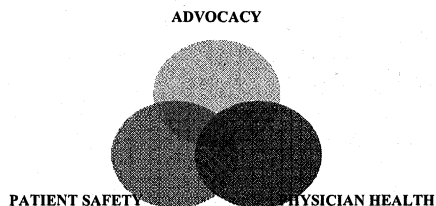
SB 109 - 2010

- ▣ Defines a bona fide relationship (MD-Patient)
- ▣ Physician must have unrestricted medical and DEA licensure
- ▣ Addresses physician conflict of interest – physician can not be employed by the dispensary
- ▣ Allows CMB to examine care of providers
- ▣ Two physicians need to independently examine those patients < 21 years old.

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Medical Boards and Physician Health Programs

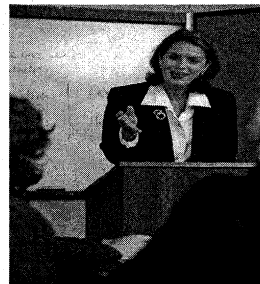
OVERLAPPING MISSIONS



Colorado Medical Board (CMB) Physicians Using MMJ

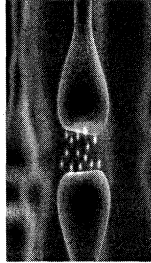


Colorado Physician Health Program

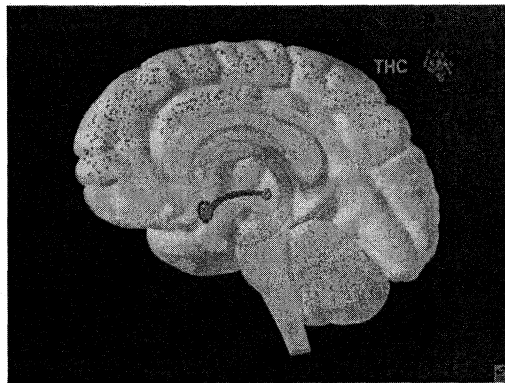
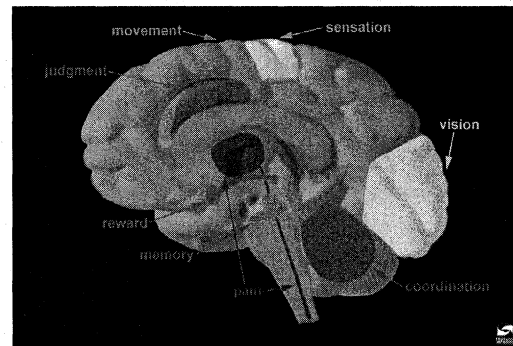


Cannabinergic system

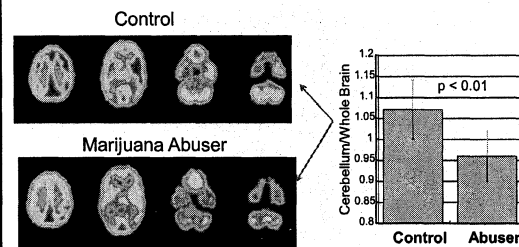
- ▣ Two main cannabis receptors
- ▣ CB1 – present throughout CNS
 - Hippocampus (short term memory)
 - Cortex
 - Olfactory areas
 - Basal ganglia (motor activity)
 - Cerebellum (motor coordination)
 - Hypothalamus/Limbic (appetite/sedation)
 - Spinal cord
- ▣ CB2 – located peripherally, linked with immune system
 - Spleen
 - Immunologic cells (B lymphocytes, natural killer cells)



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The Lower Baseline Cerebellar Metabolism in Marijuana Abusers is likely to Result in Motor Deficits



Source: Volkow et al., Psychiatry Research: Neuroimaging, 67, pp. 29-38 (1996).

Marijuana and Cognitive Impairment

Messinis et al. Neurology 2006;66:737

- ▣ Use of 4 joints or more per week resulted in a decrement in mental test performance, subjects who smoked regularly for a decade or more did the worst
- ▣ Long-term marijuana users were impaired 70% of the time on a decision making test, compared to 55% for short-term users and 8% for non-users



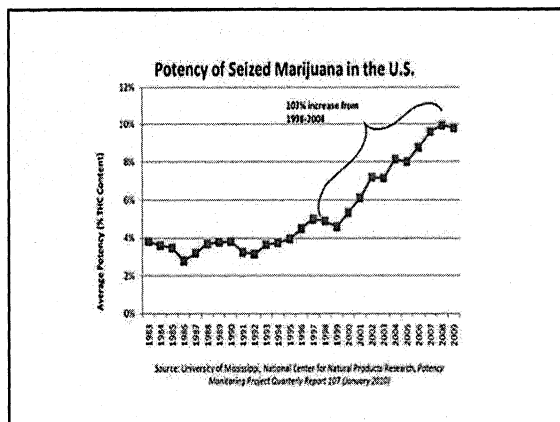
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Effects of Marijuana Intoxication and Pilot Performance

Am J Psychiatry 1985;142:1325-1329

- ▣ Ten experienced licensed private pilots trained for 8 hours on a flight simulator landing task
- ▣ Each smoked a THC cigarette (19 mg)
- ▣ 24 hours later their mean performance on the flight task showed trends toward impairment in all variables, some tasks showed significant impairment
- ▣ Despite the deficits, the pilots reported no awareness of impaired performance

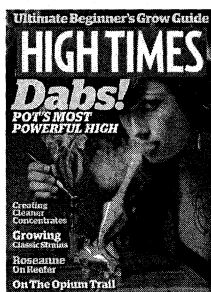




Blasting - Dabs (90%)



Butane (Infused) Hashish Oil - BHO



Butane cans and mind altering substance; what could go wrong?



Toxicology of Marijuana

- Levels, what do they mean?
 - Poor correlation between serum THC concentrations and degree of intoxication
 - MJ cigarette with 1.75% THC has peak serum concentration of 85ng/ml in 8 min
 - Therapeutic concentration for nausea/emesis is > 10ng/ml
 - Cognitive effects with levels as low as 3ng/ml
 - Proposed cut off for driving is 5ng/ml, while very controversial, adopted in Colorado

Metabolism of Marijuana

- Massive first pass metabolism via the oral route - only 10-20% reaches systemic circulation unchanged - takes 30 - 60 minutes to achieve an effect - key side effect on CNS can be dysphoria rather than euphoria
- Via the lungs - onset of action within seconds - "high" experienced with serum concentration of 3 ng/ml, produced by as little as 2-3 mg D9-THC, average "joint" contains 0.5 - 1.0 g of cannabis

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Physicians Using MMJ

- ▣ The Colorado Physician Health Program Policy
 - Physicians suffering from a debilitating condition requiring "treatment" with marijuana will be considered unsafe to practice medicine with reasonable skill and safety.
 - This is due to significant cognitive impairment associated with the use of MJ
 - This is also due to the fact that it is virtually impossible to establish a stable dose/serum level due to variable concentrations of THC
 - No case law exists regarding this issue

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Amendment 64

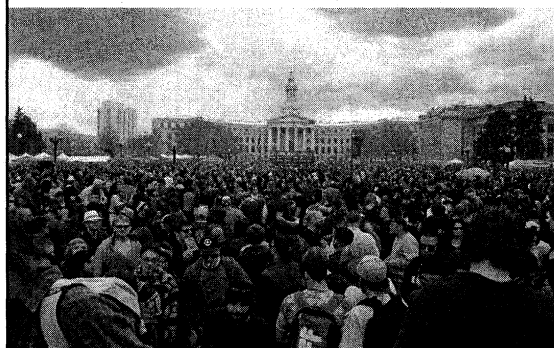
- ▣ Ballot initiative to legalize marijuana
- ▣ "Medical Marijuana" - A Trojan horse for the legalization of recreational marijuana



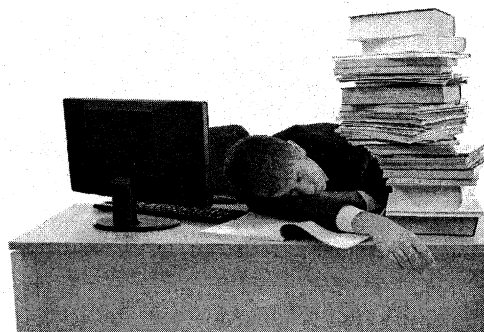
November 6, 2012



April 20, 2013

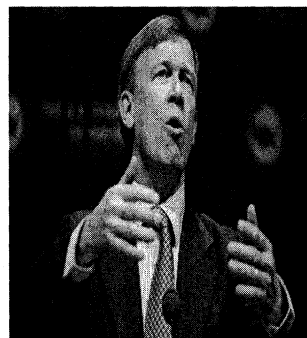


Rules and Regulations



Federal Response to Legalization of MJ

- ❑ Despite Amendments 20 and 64, MJ use is still in violation of federal law:
 - Can prosecute growers, distributors and possessors
 - DEA has denied petition to remove MJ from the Schedule I classification
 - Physician practices may be profiled and investigations initiated for suspicious MJ recommendation patterns



Governor John Hickenlooper warned that given federal law, the state's residents shouldn't "break out the Cheetos or Goldfish too quickly."



COLORADO PHYSICIAN HEALTH PROGRAM

Policy for addressing the recreational use of marijuana among physicians



DSM V Criteria

- ❑ Taking the substance in larger amounts or for longer than intended
- ❑ Wanting to cut down or stop using the substance but unsuccessful in doing so
- ❑ Spending a lot of time procuring, using, or recovering from use of the substance
- ❑ Cravings and urges to use the substance
- ❑ Not managing to do what you should at work, home or school, because of substance use

DSM V Criteria (cont)

- ❑ Continuing to use, even when it causes problems in relationships
- ❑ Giving up important social, occupational or recreational activities because of substance use
- ❑ Using substances again and again, even when it puts the you in danger
- ❑ Continuing to use, even when the you know you have a physical or psychological problem that could have been caused or made worse by the substance

DSM V (cont)

- ❑ Needing more of the substance to get the effect you want (tolerance)
- ❑ Development of withdrawal symptoms, which can be relieved by taking more of the substance

Comprehensive Evaluation

- ▣ Extended clinical interview(s)
- ▣ Computerized health questionnaire
- ▣ Cognitive Screening
- ▣ Assessment for comorbid conditions
- ▣ Laboratory evaluation
- ▣ Workplace and personal collateral information

Urine Monitoring

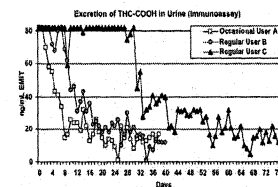


Urine Drug Screening

- ▣ Show whether the client has used cannabinoids within the past 1-90 days
- ▣ Does provide a quantitative level but clinical significance is not direct
- ▣ Can monitor to show use has stopped – values drift to zero
- ▣ Complicated by the fact that cannabinoids are stored in the fat

How will CPHP Evaluate and Monitor?

Urine Testing - Regular Use



(P. Griebelmeier, Cannabisabusum, Straßenverkehr und Arbeitswelt, from GM Ellis, et al., Excretion patterns of cannabinoid metabolites after last use in a group of chronic users, Clin Pharmacol Ther 1985;38(5):572-578.)

Blood Monitoring

- ▣ Assesses for THC in the blood stream
- ▣ Directly related to the amount of active rather than stored psychoactive substance (THC)
- ▣ Detectable blood levels up to 2 weeks after use in heavy users – leeching from adipose tissue
- ▣ DUI in Colorado – 5 nanograms/ml

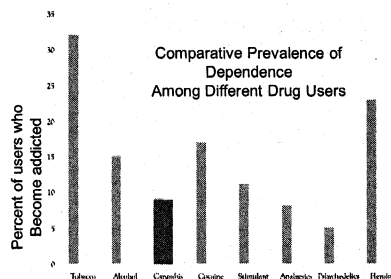
Education

- ▣ Discussions about professionalism
- ▣ Counseling about risks associated with recreational marijuana use:
 - Professionally
 - Legally
 - Personally

Professionalism



Addiction: About 9% of cannabis users may become dependent



Source: Anthony et al. Exp. Clin. Psychopharmacol. 2(3), pp.244-268 (1994)

Physicians Recommending Medical Marijuana

- ❑ Should get a thorough history - medically, psychiatrically and substance abuse - keep a chart and have a patient/physician relationship
- ❑ Should receive no pecuniary remuneration from caregivers or dispensaries
- ❑ Will need to attempt to decide what level of marijuana use is most appropriate
- ❑ Will need to recommend patients not drive etc. when under the influence
- ❑ Should warn patients to avoid exposing children and adolescents to marijuana smoke
- ❑ Will need to follow patients closely for side effects and unintended consequences
- ❑ Obtain informed consent

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The Medical Practice Act

- ❑ Physicians should maintain adequate malpractice coverage - let the buyer beware!
- ❑ Physicians should be able to evaluate for SUDs
- ❑ Physicians should engage in continuing education (No certification available for MMJ practice)
- ❑ Physicians should only practice within their scope of expertise



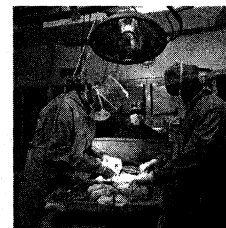
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Colorado Physicians Insurance Company: COPIC

- ❑ Unusual route of administration of a drug (i.e. no FDA approved drug is smoked!)
- ❑ Contradicts movement toward practicing evidence based medicine
- ❑ Abrogation of the role of the FDA
 - Evidence of efficacy and safety
 - Concerns about potency and purity (unregulated)
 - MJ bypassed scientifically based drug approval procedure
 - No standards for therapeutic dosing
 - No post marketing surveillance
- ❑ MJ has bypassed the Colorado Prescription Drug Monitoring Program (despite being a Schedule I drug) because it is "recommended" rather than prescribed

Legalization of Recreational MJ

- ❑ Still a violation of federal law
- ❑ Any institution accepting federal money may be at risk of losing that federal support
- ❑ Many local hospitals and universities are adopting zero tolerance policies



Closing Thoughts

- ▣ Recognition of the distinction between decriminalization and medicalization is critical
- ▣ Need to dispassionately study the therapeutic properties of MJ's many compounds separately
- ▣ Develop delivery systems that are less prone to abuse
- ▣ Approving medications by ballot initiatives and state legislative actions sets a dangerous precedent for public health
- ▣ Recreational use of marijuana in Colorado: ???

North Star BHS – CME Activity Course Evaluation Form

Date: 10/14/2014 Starting Time: 5:00pm Location: North Star Behavioral Health - Anchorage

Topic: Medical Effects of Marijuana / The Colorado Experience with Legalization

Presenter(s): Doris Gundersen, MD PC – Medical Director Colorado Physician Health Program

At the conclusion of this activity, participants should be able to:	Not at All	Slightly	Moderately	Mostly	Completely
Describe the impact of legalization of recreational marijuana on emergency room visits, motor vehicle accidents and crime					
Widen differential diagnosis for psychosis and anxiety to include marijuana.					
Implement DSM-5 diagnostic criteria for marijuana addiction and withdrawal.					
Integrate enhanced drug screening in the framework of ongoing psychiatric evaluation.					

Was the presentation commercially biased in any manner?

Yes ☐ No ☐

Based on this activity, what will you do differently in your practice? _____

Topics of Interest for future Seminars: _____

Printed Name of CME participant: _____

Physician Yes ☐ No ☐

Signature of CME participant: _____

Agency/Organization: _____

Email: _____

Are you on our email distribution list? Yes ☐ No ☐

If not – do you wish to be added for future CME events? Yes ☐ No ☐