Uniform Standards

Recommendations for changes to Uniform Standard #4 from the California Society of Addiction Medicine (CSAM)

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CSAM is a state chapter of the American Society of Addiction Medicine (ASAM)

CSAM is presenting these recommendations as legislatively mandated in SB-796 (Hill) signed by the Governor on October 8, 2017 as follows:

SECTION 1. Section 315

(d) Notwithstanding any other law, by January 1, 2019, the committee shall review the existing criteria for Uniform Standard #4 established pursuant to paragraph (4) of subdivision (c). The committee's review and findings shall determine whether the existing criteria for Uniform Standard #4 should be updated to reflect recent developments in testing research and technology. The committee shall consider information from, but not limited to, the American Society of Addiction Medicine, and other sources of best practices.

Our Review of the Uniform Standards

CSAM formed a task force of subject matter experts to deliver a list of recommended changes and additions that would:

- Conform to the practice of evidenced-based medicine
- Address what is currently known about the science in the treatment of Substance Use Disorders and evolving substance use testing practices
- Address best practices across the country and abroad for the effective operations of a PHP, including but not limited to:
  - Protecting the public
  - Attracting self-referrals for early identification and referral to treatment
  - Achieving high successful completion rates
  - Effective rehabilitation of physicians
  - Maintaining sustainable funding

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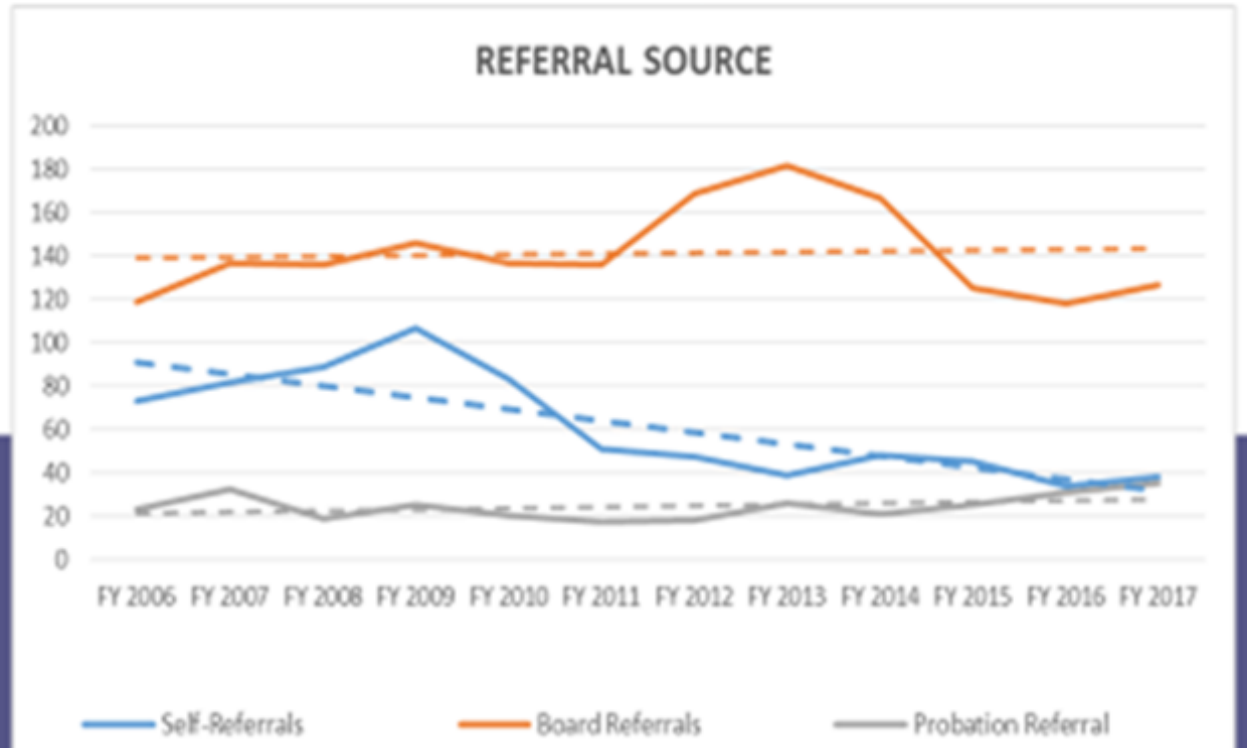
**Members of the California Society for Healthcare Attorneys*

Guidance from the Federation of State Medical Boards

- PHPs and regulatory agencies agree that public protection is paramount
- Safe re-integration of the recovering physician back into the workforce constitutes the ideal scenario
- A PHP should be empowered to conduct an intervention based on clinical reasons suggestive of potential impairment
- Unlike the board, which must build a case capable of withstanding legal challenge, a PHP can quickly intervene based on a reasonable concern
- The PHP can, therefore, be a significant benefit to public safety and a cost savings to licensure boards
- Since 1995, FSMB policy has supported physician remediation via an effective PHP as an alternative to, or in conjunction with, discipline

The enrollment in California's Diversion Programs since Uniform Standards were implemented has declined:

Barriers to participation have impacted ability to help



Enrollment in states that have well-functioning PHPs

- **Massachussetts' PHP**: in FY 17 "more than **400** physicians and medical students have been helped" with "192 new physicians and medical students" referred; in the history of the MA PHS more than 3,000 physicians have been assisted.
- **Minnesota's PSP**: 299,734 licensed and regulated health professionals; 1.88 out of 1000 licensed/regulated HP is active in the HPSP; 1% growth from the previous year, but following a 5% jump in the from FY 15 to FY 16.
- **Colorado's PHP**: 27,668 health professionals in "Active License Status in Colorado"; **783** clients served in FY 17, of which 293 were new; self-referrals alone were up 3% from the previous year.
- **Alabama's AL PHP**: 60 referrals for FY 17; history of 2,390 referrals since 1990 – of those there are **292** active assistance agreements, up nearly 4% from the previous year.
- **Washington's PHP**: **189** referred in FY 17; met with 130 of those referred.

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Overview

- What is the frequency of drug testing is needed to detect use
  - A Case Study of Drug Testing and Sanctions for California
- What type of program is needed to deter use
  - HOPE Program
  - 24/7 Sobriety Program
- Guiding Principles
- Uniform Standard #4
- Advances in drug testing practices

Data on drug detection

- Weekly testing generates a 35% chance of detecting a given incident of drug use
- Twice-weekly generates a 80% chance of detecting a given incidence of drug use
- Arrange sanction penalty less for admitting drug use than for denying it and testing positive
- Impact of a sanction on a behavior is a rapidly declining function of the time delay between the behavior and the sanction

Opportunities and Barriers in Probation Reform: A Case Study of Drug Testing and Sanctions, UC Office of the President California Policy Research Center Papers Mark Kleiman, et al 2003

If you don't clean up your room right now there is a 40% chance that a month from now, I will ground you for two years!

Criminologist James Q. Wilson's analogy for how we respond to criminal offenders

What we know from contingency management studies

- Across substances, more than 150 RCTs show that behavior is responsive to immediate, transparent consequences, not confusing consequences
- Addiction shortens time horizon and lessens executive control, but contingency management surmounts this
- Criminal justice is a different context than voluntary treatment, but principles translate

M Pendergast, et al Contingency management for treatment of substance use disorders: a meta-analys 2006

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Exemplars of the New Paradigm

- HOPE Probation
- 24/7 Sobriety

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Challenges of Probation

- Low social capital offenders
- More serious co-occurring problems
- Overworked staff
- Confusing rules, inconsistent rewards and punishments

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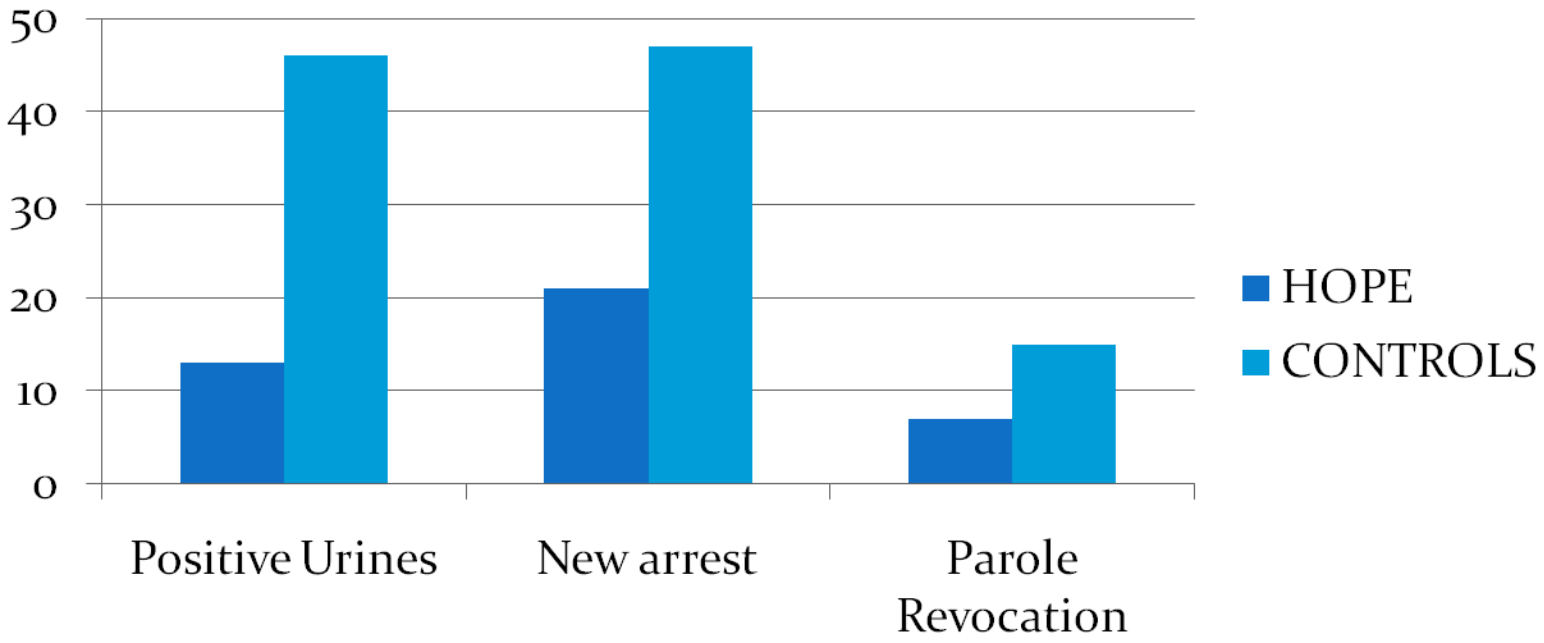
HOPE Probation for drug-involved offenders in Hawaii

- All probationers given full orientation to rules and onus of responsibility placed on them
- Probationers are required to call a hotline every weekday to determine if they are randomly selected
- During their first two months in HOPE, probationers are randomly tested at least once a week Monday - Friday. Good behavior through compliance and negative drug tests is rewarded with less regular testing
- Positive urine or missed random urinalysis results in *prompt* arrest and *certain*, *modest* punishment (brief jail stay)
- Treatment offered

1-year randomized trial findings of HOPE versus usual probation (n=493)



Source: Hawken, A., & Kleiman, M. A. R. (2009). Managing Drug Involved Probationers with Swift and Certain Sanctions: Evaluating Hawaii's HOPE. Report to National Institute of Justice, Washington, D.C.

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www.dwiblog.org

Drunk drivers in the U.S. Northern Plains

- Over 10,000 Americans a year die in alcohol-involved car accidents
- The peak states are in the Northern Plains (e.g., Montana, North Dakota, South Dakota)
- Typical penalties, e.g., license removal, widely ignored
- A county prosecutor (Larry Long) decided to innovate

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24/7 Sobriety for repeat drunk drivers in South Dakota

- All offenders get careful orientation to program rules
- Twice-daily breath testing or alcohol-sensing bracelet rather than urine screen
- Alcohol use or no show results in *prompt* arrest and *certain*, *modest* punishment (1 night in jail)
- Nearly self-sustaining financially because offenders pay for own testing

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Key Outcomes of RAND Research

- Over 99% of tests are taken and negative
- Repeat drunk driving arrests down 12%
- Domestic violence arrests down 9%
- *Population* mortality reduced 4.2%

Source: Kilmer, B. et al. (2013). American Journal of Public Health, 103; Nicosia et al., (2016) Lancet Psychiatry, 3, 226-232.

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In summary, both the HOPE and 24/7 Sobriety Programs

- Give offenders simple, transparent rules, which encourages responsibility, learning and a sense of fairness
- Use swift, certain and modest contingencies
- Mandate change, offer treatment

Program demonstrated evidence of effectiveness and of cost-effectiveness

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Contingency management plus employment incentives is the science behind healthcare programs

- The science and success of healthcare professionals programs is rooted in basic and applied operant conditioning and arranged reinforcement for abstinence
- Many studies indicate employment incentives for drug abstinence are effective in initiating abstinence as a maintenance intervention
- For healing arts licensee there are high magnitude incentives - working in your hard earned career in healthcare
- Effective programs include multiple interventions:
  - Clinical oversight by the medical director
  - Workplace awareness, worksite monitor
  - Testing using multiple matrices
  - Support and monitoring groups

R DuPont et al Setting the standard for recovery: Physician Health Program J of Substance Abuse Treatment 2009

Guiding Principles

Principles followed in choosing the recommended wording for modification of Uniform Standards that will govern the programs for all Licensing Agencies under Department of Consumer Affairs – Substance Abuse Coordinating Committee:

1. The Board's responsibility to protect the public should be exercised in ways demonstrated to be effective.

2. The program should be able to be implemented in a realistic and practical manner; standards that are unreasonably difficult to meet should be modified.

3. The programs are not treatment programs; they are monitoring programs. Because the elements of a monitoring plan are considered part of after care (an extension of treatment) and are based on the treatment goals, and because implementing a monitoring program requires the understanding of treatment history and the application of clinical judgment, monitoring should be under the direction of a qualified clinician.

Guiding Principles

4. The responses required by the Uniform Standards to "major" and "minor" "offenses" should be based on the understanding of the progression of the stages of treatment and recovery for the diagnosis of substance use disorders of all types defined in DSM V. Each program's responses should be in line with the therapeutic responses described in commonly accepted guidelines.

5. The program should be under the direction of a Medical Director. Others in positions where judgment or interpretation is a factor (such as group facilitators and case managers) should be required to be licensed clinicians with clinical experience.

6. All clinical details should be deleted from regulation. All clinical information and all clinical determinations and decisions should be the responsibility of the program's Medical Director or his/her designee.

7. The cost of an appropriate and effective program is too great to be borne solely by participants. The costs should be spread across all licenses in the state. The program should be supported primarily (not necessarily exclusively) by licensure fees from all licensees in the state.

Guiding Principles

8. Those who enter the program will have voluntarily relinquished their rights before their licensing agency in order to gain the benefits of participating in the program. Nonetheless, the program's governing regulations, policies and procedures should recognize and honor the individual's rights to the extent that is reasonably in line with the purpose of the program.

9. Within appropriate limits, all participants have the right to privacy.

10. Within appropriate limits, participants have the right to pursue their profession.

11. Participants have the right to timely and appropriate treatment and monitoring methods that meet currently accepted standards and acknowledged best practices.

12. The program's governing regulations regarding reporting names of participants to the public should be different for "self-referrals" than they are for participants referred into the program by the licensing agency.

Why changes to Standard #4 are necessary

- Originally, one specimen, urine, was used in drug testing programs, policies procedures were built around that specific specimen
- Drugs of abuse are rapidly absorbed into the bloodstream then distributed to various tissues, excreted into saliva, urine and deposited into hair and finger and toe nails
- Each specimen is unique in its concentration of drugs, detection times
- It is now possible to consider multiple sources of specimens to detect an individual's drug use
- Urine is difficult to collect, direct observation is limited and expensive
- Alcohol detection has improved: Cellular photo digital breathalyzer and continuous transdermal alcohol monitoring

Key Areas of the Standard requiring change

- Frequency of testing
- Randomnicity
- Method of notice to the licensee
- Number of hours between the provision of notice and the test
- Specimens tested
- Standards and procedures for specimen collectors
- Permissible locations of testing

Key Elements for a PHP Substance Testing Protocol

- The program shall require participants to abstain from the use, consumption, ingestion or administration of prohibited substance unless an exemption is specified in the participants agreement with the program
- The program shall have a protocol governing the aspects of the testing required to determine compliance with the agreement between the participants and the program
- Protocol will include: frequency schedule, any exceptions, consequence to the licensee for non-compliance with testing schedule as described in Uniform standard 8, 9 and 10
- Protocol shall describe the biological specimens to be tested and the method of testing to be used
- Will also describe how additions to the protocol will be made as additional methods become accepted

Importance of this issue

- We cannot tolerate impaired professionals in safety-sensitive positions
- There are many causes for impairment
- Approximately 10% of every profession that has been studied will have a problem with substance use during their career including all health professionals
- Systems have been developed for early detection, treatment and monitoring that work: Airlines (FAA HIMS Program), Nuclear Regulatory Commission (Safe Harbor Program), 47 state Physician Health Programs, Lawyer Assistance Programs, etc.
- We know it works and we can develop a system in CA

What we have now is not working

- Health professionals are frequently not referred until there is a crisis and a report is required (805 report)
- The regulatory board investigations can take many months while the licensee goes on without intervention or help
- Monitoring is conducted by regulation instead of taking advantage of the science of substance use disorder monitoring
- Case example

What works – other states, airlines, NRC…

- Educate hospitals, medical groups, patient groups, others that there is a program for early identification that is therapeutic, rather than only punitive, that can help the colleague and protect patient safety and their career
- Accept referrals and take **immediate action** following confirmation that concern is legitimate
- Intervene on and refer for thorough evaluation (utilizing leverage of necessity to report if unresponsive)
- Require thorough effective treatment
- Require extended monitoring with specified consequences for every level of relapse
- Report to the regulatory agency any lack of cooperation that could lead to risk

Features that make it work

- Must have competent professional leadership (MRO, Addiction Medicine, experience)
- Must have a system that is rehabilitative and non-punitive that people will refer to
- Colleagues are hesitant to refer a colleague because they don't want to be involved in destroying the person's career
- If the program we develop is fair and consistent, it will attract those who have had an incident
- Monitoring is complex and must take into account the drug(s) to be monitored, the panels, the matrices to be tested, the frequency, etc. (cannot be done well by legislation)

20 Steps to Foolproof Drug Testing

1. Signing of a detailed monitoring agreement with the participant
2. * Development of competent collection sites
3. * Provision of proper urine collection kits to collection sites
4. Provision of financial arrangements between collection site, participant, and lab
5. * Quality control and regular periodic follow-up of collection site to ensure that proper collection methods are being maintained
6. * Periodic questioning (during quarterly reviews) of the participant to insure that specimen collection is being performed properly

** problem areas*

20 Steps to Foolproof Drug Testing, (cont'd)

7. * Notification method to inform participant to obtain urine drug testing (random, for cause, etc.)
8. * Monitoring no-call and no-show report w/ appropriate action
9. Monitoring of compliance of submission of specimen within appropriate time frame following notification
10. Competent, chain of custody testing at a qualified lab
11. Appropriate testing of specimens (i.e. proper test, proper analytes, etc.) to include drugs of abuse used by health professionals
12. Method for varying drug test panel as appropriate based on clinical situations, drug of choice, trends, etc.

** problem areas*

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20 Steps to Foolproof Drug Testing, (cont'd)

13. Determination of level of relapse
14. Reporting of relapse to appropriate authorities as needed or agreed
15. Intervention with participant and referral for appropriate reevaluation
16. Work with evaluation personnel to assure transfer of information and thorough reevaluation and receipt of reports
17. System for routine confirmation (usually by GC/MS or LC/MS) of all screened positives results

20 Steps to Foolproof Drug Testing, (cont'd)

18. * Review of drug testing reports by Medical Review Officer or other qualified personnel, with appropriate investigation, interview with participant to exclude appropriate use under physician care and reporting of positives
19. * Entry of report notification and submission times into a database for analysis, storage, comparison, and review
20. Review of all non-negative reports (including: dilute, positive, adulterated, invalid, or delayed reports) by staff

** problem areas*

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Daily Contact and Testing Frequency:

- Licensee will make daily contact to determine if drug testing is required
  - Recommend testing on a random basis, preferably generated by a computer program
  - Recommend back-to-back testing as well as testing at different intervals
- Drug testing may occur on weekends and holidays

Elements Taken into Consideration When Determining the Testing Schedule:

- Evidence that a licensee has successfully completed or is currently participating in a treatment or monitoring program
  - Providing test panels used in the treatment program are reasonably comparable to the panels used by the program
- Increase in the frequency of testing as needed
  - Missed tests, failure to comply
  - Consequences outlined in the program's protocol and licensees agreement

Considerations Prescribed Medication:

Prescribed Medication

- Open communication with treating physician or treatment team
  - Acute time-limited course
  - On-going treatment regimen
- Periodic reports, review and readjustment, possible cognitive testing, etc.

Recommendations for Collection Sites:

- Specimen collectors and testing locations laboratories will have appropriate training or certification
- Requirements of the protocol for observed collection or meets the requirement if observed collection is not available

Recommendations for Testing Protocol and Reporting Times:

- Program's protocol shall specify "reflex tests" for its screening tests
- Collection site shall submit specimen within one business day
- Legally defensible results within 7 days of the receipt of the specimen
- Program will be notified of any confirmed positive within one business day and negative results within 7 business days

Advancing Science of Substance Use Monitoring

- Matrices: blood, breath, urine, sweat, hair and nails
- Matrices have different windows of detection
- Combined determination of several markers allow complementary information
- Real-time monitoring of alcohol using smart-phone application coupled with a Bluetooth breathalyzer
- Chemical analysis using sweat patches worn continually for a week
- Not yet available but undergoing clinical trials – small implantable device that communicates by bluetooth to detect opioids

Questions?

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