



ISSUE MEMORANDUM

DATE	May 13, 2009
TO	SB 1441 Substance Abuse Coordination Committee
FROM	SB 1441 Uniform Standards Staff Working Group Presented by: Anne Sodergren, California State Board of Pharmacy
SUBJECT	SB 1441 Uniform Standard # 4

SB 1441 REQUIREMENT

(4) Standards governing all aspects of required testing, including, but not limited to, frequency of testing, randomicity, method of notice to the licensee, number of hours between the provision of notice and the test, standards for specimen collectors, procedures used by specimen collectors, the permissible locations of testing, whether the collection process must be observed by the collector, backup testing requirements when the licensee is on vacation or otherwise unavailable for local testing, requirements for the laboratory that analyzes the specimens, and the required maximum timeframe from the test to the receipt of the result of the test.

DRAFT UNIFORM STANDARD #4

If the board determines that a licensee shall be subject to drug testing, the following minimum standards apply:

1. Licensees shall be tested at least 18 times per year for the first three (3) years of continual abstinence. After the first three (3) years, licensees shall be tested at least 12 times per year.
2. The scheduling of tests shall be done on a random basis, preferably by a computer program.
3. Licensees shall be required to make daily contact to determine if testing is required.
4. Licensees shall be required to test on the date of notification as directed by the board.
5. Specimen collectors must either be certified by the Drug and Alcohol Testing Industry Association or have completed the training required to serve as a collector for the U.S. Department of Transportation.
6. Specimen collectors shall adhere to the current U.S. Department of Transportation Specimen Collection Guidelines.
7. Testing locations shall comply with the Urine Specimen Collection Guidelines published by the U.S. Department of Transportation, regardless of the type of test administered.
8. Collection of specimens shall be observed. **(Continued on next page)**

DRAFT UNIFORM STANDARD #4 - Continued

9. Prior to vacation or absence, alternative testing location(s) must be approved by the board.
10. Laboratories shall be certified by the National Laboratory Certification Program.
11. A collection site must submit a specimen to the laboratory within one (1) business day of receipt. A chain of custody shall be used on all specimens. The laboratory shall process results and provide legally defensible test results within seven (7) days of receipt of the specimen. The appropriate board will be notified of non-negative)test results within one business day and will be notified of negative test results within seven (7)business days.

DISCUSSION**Frequency**

Discussion from the workgroup included if consideration should be given to establishing an alternate testing frequency when a licensee is not working. Concern was raised that the cost of the tests could be problematic with such individuals.

Comments received from Julianne Fellmeth, Center for Public Interest Law, stated that more frequent testing during the first year of participation (e.g., 3-5 times per week) is appropriate especially if the participant is being permitted to practice. The workgroup considered these comments and determined that while the minimum testing frequency established is appropriate, no maximum is identified, thereby allowing a board to establish a higher frequency in the number of tests required.

Elinore F. McCance-Katz, M.D., PhD suggested that the testing frequency be increased to allow testing up to 48 times per year. After discussion and consideration, the workgroup is recommending the minimum number of tests (18) and is no longer providing a maximum number of tests that may be required. This change will allow a board to determine the appropriate number of annual tests at any rate at or above 18 per year during the first three (3)years of continual abstinence.

Tom Harvath, PhD. also expressed concern with the testing frequency provided in the initial draft standard; however, he did not specify an alternative for the workgroup to consider. Dr. Horvath suggested that the standards should include some method for applying reduced testing frequency and when that application should be allowed. The workgroup believes that the testing frequency should be determined by the board or its designee, but shall not fall below the minimum number of eighteen (18) tests specified in the standard.

Public comment during the hearing included concern over the frequency of tests relating to the cost for these tests. The workgroup determined that the minimum number of tests established is appropriate. The workgroup is recommending that the department secure a

department-wide contract for implementation of this standard. If such a contract is procured, the department may be in a position to negotiate costs.

Randomnicity

Dr. Horvath suggested that scheduled testing is easier than random testing on the individuals being tested as it is a known event and can be planned for. He continued to state that random testing requires oversight by a diversion program and drug testing facility and is cumbersome for participants. The workgroup considered this comment, but believes that random tests are appropriate.

Daily Contact

Public comment during the hearing indicated that daily contact should not be required and that the language should be changed to make this requirement permissive. The workgroup believes that daily contact should be mandatory. A department-wide contract will allow for implementation of this provision by making it a requirement in the scope of service for the contractor.

Testing Period

The group considered allowing 12 – 24 hours after a licensee is advised of the requirement to submit a specimen, but determined that requiring the deposit of a specimen the same calendar day is the appropriate minimum standard.

Ms. Fellmeth suggested that the minimum standards must find a way to control the number of hours between the moment a participant knows he must be tested until the actual test. She also suggested that an appropriate requirement for collection be within six (6) hours of notice. The workgroup believes that the minimum standard established is appropriate. There is nothing in this standard to prohibit a board from establishing a shorter timeframe. Should the department elect to pursue a department-wide contract, the availability of a check in system could be specified to include the hours when the system may be accessed as part of the contract.

Specimen Collectors

The workgroup determined that the appropriate minimum requirements for specimen collectors are those established by the U.S. Department of Transportation. These guidelines can be downloaded at:

<http://transit-safety.volpe.dot.gov/Publications/substance/DOTurine/HTML/urine.htm>

Observed Testing

Public comment during the public forum questioned the legality of observed testing. DCA counsel advised that observed testing is allowed.

Public comment also suggested that observed testing may cause an increased wait time to the licensee who may need to stay at a laboratory for an approved observer to arrive. Observed tests could also result in an increased cost to the licensee. The workgroup determined that all tests must be observed.

Vacation

Dr. McCance-Kantz suggested removing this portion of the standard. The workgroup modified the minimum requirement; however, SB 1441 specifically requires the standard to address backup testing requirements when the licensee is on vacation. It cannot be totally eliminated.

Laboratories

The workgroup recommends requiring that all laboratories processing results be certified by the National Laboratory Certification Program. A list of the current labs can be obtained from the following link:

http://www.workplace.samhsa.gov/drugtesting/level_1_pages/certifiedlabs.aspx

General information on this program can be downloaded from:

http://www.workplace.samhsa.gov/DrugTesting/Files_Drug_Testing/Labs/Natl_Lab_Cert_Prog_Background1007.pdf

A comments received during the public forum addressed access to a Medical Review Officer (MRO) for evaluating laboratory tests. As part of the certification program, a laboratory must use the services of an MRO.

Processing Time for Testing

The group had significant discussion on the appropriate minimum time frame for test results to be provided. The group determined that the standard should reflect a couple of time frames: (1) the time from collection to shipping and (2) the processing time from receipt in the lab to receipt of the legally defensible results. The group agreed that all specimens should be sent to the laboratory within one (1) business day.

There was significant discussion both in the workgroup and during the public forum regarding the minimum standard for processing laboratory results. Anecdotal suggestions included requiring the results to be provided within three (3) days; however, the workgroup is concerned that the time to provide legally defensible test results may take longer.

Additional Public Comment Outside the Scope of the Standard

A question was asked about who would receive the results of the test results. The appropriate board would have access to the test results.

Concern was raised about the use of the EtG test. The proposed standards do not establish any testing panels nor do they require the use of the EtG test.

Workgroup Recommendation

The workgroup recommends that the department secure a contract that will allow all boards to use the same vendor for specimen collection and processing. The group believes that a single contract for such services will ensure consistency and uniformity in the implementation of the standard while keeping the costs reasonable to the licensees. Further, this will assist smaller boards, or those without a current vendor, to immediately allow for the testing as required in this standard. As part of the contract, it is recommended that the department specify that collection center hours allow for evening and weekend testing.

PROS

Many of the standards specific to testing collection and specimen handling are consistent with or based upon the guidelines established by the U.S. Department of Transportation.

Requiring the certification of laboratories through the National Laboratories Certification Program ensures consistent handling and processing of test results.

The minimum number of tests provided will help to identify relapse and allow for licensees to be randomly tested.

Requiring a licensee to submit a specimen on the same day as noticed will eliminate the ability of a licensee to “flush” their system overnight. Further, the established certification of the laboratory will include creatine and pH levels which can be a sign of a licensee “flushing” their system. Further, the standard is broad enough to allow a board to determine on a case-by-case basis if a licensee should be required to submit a specimen more quickly, e.g., before 10:00 a.m. or within six (6) hours of notice.

CONS

Comments made at the first SB 1441 Substance Abuse Coordination Committee meeting indicated that some do not believe that you can confirm abstinence from a prohibited substance unless you test a person daily.

The costs for drug screening may be problematic for some licensees, especially those that are restricted from working. However, each board’s consumer protection mandate takes higher priority.

PUBLIC COMMENT

Comments submitted by the public, both in writing and at the public forum, are included in the analysis above.