AMERICAN COLLEGE OF
OCCUPATIONAL AND
ENVIRONMENTAL MEDICINE

8400285

July 12, 2004

Substance Abuse and Mental Health
Services Administration
5600 Fishers Lane, Rockwall II
Suite 815
Rockville, Maryland 20857

Re: Docket 04-7984

To Whom It May Concern:

The American College of Occupational and Environmental Medicine (ACOEM) is pleased to have the opportunity to provide comments to SAMSHA on the Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs.

ACOEM membership includes over 5,000 physicians and is the world's pre-eminent and largest organization of physicians specializing in the practice of preventing, assessing, and treating occupational and environmental health disorders. Many ACOEM members perform Medical Review Officer (MRO) services and are devoted to the promotion of healthy and productive workers. We continue to support wholeheartedly the role of drug testing to meet the goals of preventing occupational injury, illness, and disability.

ACOEM provides their membership with the elective opportunity to join special interest groups, known as sections. The Medical Review Officer Section is one such group, and has, as in the past, provided specific direction and insight into the College's formal comments concerning these and other areas of Federal Drug Testing Guidelines.

ACOEM encourages MRO's to keep abreast of the ever-changing landscape of drug and alcohol testing science and technology. ACOEM also provides not only its membership, but other physicians, continuing medical education in the area of MRO practice.

ACOEM and its MRO members have wrestled with the alternative testing and point of collection testing issues for many years and are well-positioned to provide input and insight to the Proposed Revisions where applicable. We champion the efforts of Federal Agencies who have given the MRO additional "gatekeeper" responsibilities, such as what occurred with the revisions to 49 CFR Part 40 that went into effect in 2001. As has been noted in the introduction to the Proposed Revision, many sections mirror the language of previously implemented rules and regulations under other Federal Departments such as DOT and NRC, and the College supports such collaboration and consistency. To that end, ACOEM offers the following recommendations, identified by Subpart within the Proposed Rule:

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1 Subpart A – Applicability. ACOEM supports the definitions as listed to be consistent with other agencies and regulations.

2. Subpart B – Specimens. ACOEM recognizes the advancement in technology concerning alternative testing methodologies, but strongly supports the communication that the institution of such be optional for agencies and not required. We understand completely the concerns of the users of drug testing services from the standpoint that currently, the ability to test for drugs of abuse has been limited to one methodology; that being urine testing. There has been widespread dialogue and discussion about the proper role and limitations of all testing methods. The College recognizes that it may be more suitable for other methods depending upon the reason for testing. For example, it has become recognized that pre-employment urine drug testing is really nothing other than an IQ test, whereby the known drug user (other than in some cases of marijuana use) simply has to sustain from use of the offending substance for just a few days in order to pass the test, knowing full well the time limitations of the detection window for drugs of abuse in urine testing.

On the other hand, the College also has a unique role in upholding and monitoring the science of drug testing, and it is this role that has many of our MRO members concerned when discussions of implementation for alternative testing methods comes to the forefront. Many of our MRO members understand the controversial nature of the science and validity of hair testing, and many also have unique experiences that are both positive and negative. In discussion with our members, it is apparent that there continues to be many questions concerning the laboratory methods employed for hair testing. The proposed rule confronts some of the issues head on, addressing appropriately, the concern of outside environmental contamination and the role of hair color as a racial bias issue. The proposed rule identifies some of the current medical literature dealing with these issues and makes an argument in favor of hair testing's validity as a result of such. The College would encourage a comprehensive review of the literature in this process.

It is clear to ACOEM that its MRO members have varied opinions concerning hair testing. The college recommends to SAMSHA that if hair testing is included in the final rule, that there is an absolute clear requirement of laboratories to conduct hair testing with uniform methodologies. These methodologies MUST include standard and reproducible methods of washing procedures to eliminate the issue of environmental contamination, and must be available to MROs for reference in case of donor or agency questions, and also in the case of potential legal challenge. Additionally, the College must be cognizant of potential racial bias concerning the deposition of drug or drug metabolite as a reflection of hair color and melanin concentration. MROs have always been sensitive to the issues of consistency and fairness across all portions of the regulation for which they have responsibility and contact. One of the MRO functions that typically goes

unrecognized is the education function; education of employers, donors, everyone. It would be difficult to explain to the donor that the differences in hair color deposition really don't make a difference. We would be much more in favor of being able to explain to the donor or others if questioned that there are well-accepted, scientifically verified "beyond doubt" mechanisms to satisfy this issue once and for all.

The College therefore believes that, if hair testing is part of the final rule, hair testing cutoff levels identify the drug user irrespective of hair color issues.

Concerning the issue of oral fluid testing, the College questions the usefulness of this collection and testing method if urine back-up collection is also required. ACOEM recognizes the limitations of marijuana detection in oral fluid testing. Consequently the College sees no benefit in instituting oral fluid testing options if a urine test also must take place. MROs, being cognizant of the burden already put on collectors for accuracy, consistency, and time, see more negatives to collecting both oral fluid and urine at the same time. Collecting both means double the paperwork, double the time, and, unfortunately, double the potential for error in the collection and documentation process.

The College supports the utilization of the table indicating appropriate testing methods in different testing situations. The College does support the concept of a longer detection window in pre-employment testing and in random testing, as there is no question that statistical significance can be attributed to identifying the remote user from the recent user. The College continues to support, as it has in the past, any measure to keep drugs of abuse out of the workplace, as the Colleges' primary focus continues to be on the health and safety of the worker.

3. Subpart C – Drug and Validity Tests. ACOEM supports incorporating the urine specimen validity testing requirements from the Mandatory Guidelines for Federal Workplace Drug Testing Programs into this revision. The requirements are in line with DOT regulations.

In consideration of SAMSHA's request for feedback concerning the importance of testing for MDMA and its analogues, ACOEM strongly endorses testing for these substances. Unfortunately, use of Ecstasy and its designer analogue drugs is of critical concern in many areas of the country and has had significant negative impact on the health and safety of the worker.

ACOEM would like to point out that it is our opinion that a serious look at the so-called "NIDA 5" needs to occur. Many MROs wonder why PCP testing is necessary. To that end, overwhelming majorities of MROs have never reviewed a positive PCP test in their practice careers. The College believes that it is time to study what really are the 5 most abused substances, and would support new requirements to identify the most used drugs of abuse in employment testing.

Concerning the proposed rule indicating lowering of the cutoff levels for cocaine and amphetamine, these newer levels will identify additional positive tests and act as an additional deterrent to drugs in the workplace. Any effort that will improve deterrence and increase safety of the workplace, ACOEM, and its MROs, support.

4. Subpart D – Collectors. We have concern for the increased knowledge burden on the collector that will occur as a result of the implementation of these rules. It is the College's recommendation that sufficient time be allowed for collectors to obtain certification in alternative method collection if these rules are adopted. We note that in Section 4.4 of the proposed rules that there is a requirement stated that the organization must retain a record of the collector's training. The College recommends that this be changed to be in line with the current DOT rules that require each collector to be responsible for their own record retention.

5. Subpart E – Collection Sites. No concern

6. Subpart F – Federal Drug Testing Custody and Control Forms. No concern

7. Subpart G – Collection Device. No concern

8. Subpart H - Specimen Collection Procedures. Concerning Section 8.2 dealing with hair sample collection, the College recommends that clear language be placed to address the situation in which there is no head hair on the donor. We would suggest that in this situation, that the collector be instructed to immediately default to a different specimen type for testing purposes.

   We note that as stated in Section 8.6, inspection of collection sites by agency personnel will be difficult. This would be a good job for MROs as many have always wanted to do this. This process may also be good and tie into the expanded gatekeeper role of the MRO as it would allow improved follow up on error correction training by actually encouraging an MRO/collector interface.

   If this were to occur, we would suggest that an additional training certification be established for MROs to be site collection inspectors.

9. Section I – HHS Certification of Laboratories and IITFs. No concern.

10. Section J – Blind Samples Submitted by an Agency. No concern.

11. Section K – Laboratory. No concern. The College supports the new requirement for universal routine reporting of laboratory concentrations on all positive specimens as frequently this is a request of the MRO, the donor, and/or the SAP.

12. Section L – Point of Collection Tests. ACOEM MRO members are also uniquely positioned concerning the area of POCT testing. We recognize the continued advancement and use of such devices in the non-Federal world of drug testing,

and understand the agency's desire to have a methodology in place in such situations where quick turn around of testing results is difficult. The College would point out that the proposed rule does not define what is "remote" or "unrealistic" when it comes to the proposal for use of POCT testing in these situations. In order to avoid confusion, we believe that this issue needs a clearer definition to avoid the potential inconsistent application for POCT testing.

We also are concerned about POCT tests from the standpoint of the collector. The proposed rule will place an already increased burden upon the collector for alternative specimen collection, and may also produce additional burden if the collector is performing and interpreting a POCT test. It is worthwhile to note that there is a significant difference between "collector" and "interpreter". We know of some collectors who may be uncomfortable in the role of "interpreter", and to that end we would encourage training requirements to reflect this and ease the collector concerns in this area.

In general, ACOEM supports the certification procedures for approval of a POCT device as indicated within the proposed rule. We have concerns, however, with the language in Section 12.6, wherein it indicates that the POCT device be able to "correctly identify at least 80 percent of the total drug challenges" and "80 percent of the total validity test challenges". This language would imply that the agency is proposing to accept a 20 percent sensitivity error rate, meaning that the POCT test could be acceptable even if it misses 20 percent of positive specimens. MROs within ACOEM would encourage the agency to revisit this requirement. If one were to err, we would suggest erring on the side of conservatism and raise the level of sensitivity at the expense of specificity. It is generally favorable to not "miss" a positive specimen and accept a higher rate of specimens that are sent forward that may screen positive and confirm negative on GC/MS.

13. Subpart M – Instrumented Initial Test Facility No concern.

4. Subpart N – Medical Review Officer. ACOEM supports the language wholeheartedly in this section to be in line with the previously established rules of MRO practice as indicated in the DOT Rule 49 CFR Part 40.

The agency has asked specifically for comments on whether the MRO should be allowed to order a test of a different specimen if the result of the initially desired specimen is invalid. We believe that this is reasonable.

The proposed rule also adds and increased gatekeeper role for the MRO in that there is a new requirement that the MRO would track minor errors that do not require corrective action or cancellation of the test. The proposed rule would require the MRO to direct the service agent to undergo corrective action to prevent the error from repeating if the minor error occurs more than once per month. In general, ACOEM supports this, as the goal of any testing program is to have as few errors as possible. We would suggest, however, that an added

requirement be listed that would require the MRO to notify employers and not just collectors when errors occur. The current "honor system", whereby the MRO assumes the collector is undergoing appropriate error correction training, may not be working as it should. Informing the client employers would help to improve compliance with this regulation.

MROs will need additional training and certification in the alternative testing methods. We would ask that the agency be cognizant of this and give appropriate time for this to occur.

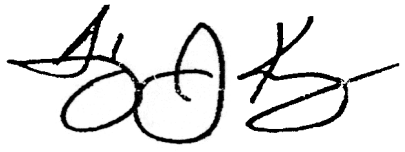
15. Subpart O – Split Specimen Tests. Many MROs have begun to question the necessity and cost/benefit analysis of split testing. Many experts in the drug-testing arena believe split testing detracts from the program, since split tests that fail to confirm almost always fail because of collection errors or adulterants. Nevertheless, the establishment of split testing procedures as a legal requirement of due process may be extremely difficult to overcome. We would suggest a review of split testing as the expansion of split testing into the alternative specimen rules may be suggested for political, and not technical, reasons.

16. Subpart P – Criteria for Rejecting a Specimen for Testing. No concern.

17. Subpart Q – Laboratory or IITF Suspension/Revocation Procedures. No concern.

Once again, the American College of Occupational and Environmental Medicine is grateful for the opportunity to provide comments to SAMSHA. We look forward to working with you and the Agency in this vitally important area. If ACOEM can be of additional help, please do not hesitate to contact us.

Very truly yours,



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