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American Association of Medical Review Officers

March 31, 2010

Mr. Mark Snider
Senior Policy Advisor
Department of Transportation
Office of Drug and Alcohol Policy and Compliance
1200 New Jersey Avenue SE
Washington, DC 20590

RE: *Notice of Proposed Rulemaking*
[Docket OST-2010-0026] RIN 2105- AD95
Comments on Medical Review Officer Standards

Submitted via *www.regulations.gov*

Dear Mr. Snider:

I am deeply concerned that SAMHSA's latest initiatives and proposals, including their decision to "approve" MRO certification boards, will have an adverse impact for DOT. SAMHSA's actions threaten the integrity of MRO credentialing and will result in the lowering of the overall qualifications and minimum training standards. This action will undermine the defensibility and integrity of the whole Department of Transportation drug testing program.

At the same time, some MRO training programs have clearly stagnated, and the credentialing process has been undermined by the development of MROCC's online exam for initial certification. (The "home study" MRO.) I would therefore like to take this opportunity to make the following comments and recommendations regarding MRO standards. I will also submit separate comments on the highly questionable merits of the IITF laboratory, the new custody and control form, and the issue of DOT's consistency with HHS guidelines.

Recommendations to DOT Regarding MRO Training and Credentialing Standards

1. DOT must require a proctored examination for initial certification for Medical Review Officers.
2. DOT should require MROs to maintain *good standing* and current certification.
3. DOT must take ownership of its drug and alcohol testing program. MRO procedures are a function of public policy and legal principles, not merely an extension of laboratory practice and technical issues. DOT should create and host a DOT/MRO advisory group to handle guidance and verification procedures. This DOT advisory group can identify areas where regulatory or statutory enhancements can be

recommended. This ongoing advisory group should include representatives from the MRO certification boards, all the operating administrations and other government regulators. A lot of the work can be done electronically.

The Establishment of Professional Standards of MRO Practice and MRO Certification

I am pleased to acknowledge that it was the American Association of Medical Review Officers (AAMRO) that established the model and template for all MRO training and certification. I was fortunate to be involved in the founding of AAMRO and the initial development of all of the existing MRO training programs. Some 20 years later, the record shows that Medical Review Officers (MROs) have been an invaluable asset to DOT and all federal drug testing programs. Thousands of examples can be cited where the MRO's professional judgment, integrity and experience resulted in protecting the individual's interests, the government's interests, the program goals and public safety. I see new examples of this every day.

AAMRO has over 6,500 certified physicians in *good standing* and has trained thousands more. I am also pleased to say that AAMRO's three-day basic training program is widely acclaimed as one of the best continuing medical education programs available for physicians, and has been for many years. AAMRO's basic training continues to evolve, and today it covers not only the nuts and bolts of the DOT program, but oral fluid testing, hair testing, prescription drug management, the special legal issues of private sector testing and special safety considerations. The AAMRO Annual Drug Testing Symposium brings together leaders in the fields of forensic toxicology, medicine, law, regulatory compliance, basic research and substance abuse to develop consensus and direction for the testing community, employers and program administrators.

AAMRO publishes the *Medical Review Officer Handbook* (now in its 9th edition). The *Medical Review Officer Handbook* is widely acknowledged as the leading reference and resource for MROs involved in both regulated and non-regulated drug testing. The text is used by most MROs, many federal agencies, healthcare providers (who are not MROs), laboratories, toxicologists, courts, lawyers, employers and internationally. It is more than simply a guide to the rules and requirements and what box to check. It provides guidance on fundamental social and business policies and legal issues, as well as thorough assessments of drug testing technology and their appropriate applications for workplace and non-workplace drug testing situations.

MROs and the drug testing community are also supported by AAMRO's web-based MRO Center, the MROALERT journal and email advisories. MROALERT has often been the first source and many times the sole source of critical technical and legal advisories to the MRO community, advising MROs on such issues as problems with 6-AM testing, the increasing pH in old urine specimens, sources of "invalid" specimens, management of paruresis, false-positives with amphetamines, and the incorrect definition of a "substituted" specimen.

It is remarkable in hindsight that development of professional standards and certification of physicians as MROs was done without a dollar of taxpayer money and in the absence of any statutes, rules or regulations. It would cost millions of dollars to re-create this today. Today, all federal drug testing programs require MROs to be certified (or at least take a national certification exam). This has been a benefit to the government, the drug testing programs and all of the stakeholders. Apparently, this is all too good to be true.

The Stagnation of MRO Training and Lowering of Professional Credentialing Standards

Now, 20 years after the creation of AAMRO, SAMHSA (HHS) will begin to "approve" the boards. This decision was made in the absence of public support and over the objections of a number of commenters. I was opposed to SAMHSA's unilateral action to approve MRO boards because I am very skeptical of both the motives and competence of SAMHSA, and because the "approval" process will turn federal MRO certification from a professional endeavor into a service commodity. However, I must now reluctantly acknowledge that at this time DOT (not SAMHSA) must take steps to maintain the integrity of its program and MRO standards.

As you know, today there are two MRO certification boards: AAMRO and MROCC. The Medical Review Officer Certification Council (MROCC) was created by the American College of Occupational and Environmental Medicine (ACOEM). This was in response to the formation of AAMRO. ACOEM was petitioned by some of its own members and me to create a certification process for MROs, and ACOEM's response was to formally oppose the measure—until AAMRO was formed (ironically, with the assistance of other ACOEM members). ACOEM then set up MROCC, which essentially copied the AAMRO template, and both boards have been operating for over 15 years.

In 2008, SAMHSA presented Dr. Robert Swotinsky at a Drug Testing Advisory Board meeting, apparently to build a public record and justification for SAMHSA's need to "approve" MRO boards. Dr. Swotinsky is one of ACOEM's key MRO training faculty and a primary author of MROCC's training materials. He stated at the webcast meeting that at the end of any ACOEM MRO training program, most physicians still do not know how to verify results for a number of situations. This is frankly unacceptable and was shocking testimony. I should note that at the end of AAMRO's training program there is no uncertainty among the physicians about how to handle the scenarios Dr. Swotinsky presented.

Dr. Swotinsky's remarks were repeated at the subsequent 2008 annual meeting of the Society of Forensic Toxicologists (SOFT) in Phoenix, Arizona. He was flown in as an invited guest of SAMHSA. Again, the purpose of his presentation was to make MROs appear incompetent (at least, the MROCC-certified MROs). He did a splendid job.

I am a member of the Society of Forensic Toxicologists, and I am a member of the board of directors of the American Board of Forensic Toxicology (ABFT). The ABFT certifies forensic toxicologists and accredits forensic toxicology laboratories. I worked for a number of years on

the board's examination committee. I was at that SOFT meeting in Arizona and I did try to set the record straight for the dumbfounded attendees.

More troubling, however, is the fact that MROCC made an astounding decision about a year ago to abandon its proctored written MRO certification exam and move the initial certification exam to an open-book, non-proctored online process. It is important to know that the most basic core requirement of all medical certification boards (as well as other professional credentialing boards like ABFT) is to have a proctored, closed-book exam. It is not simply a question of who actually took the exam or even "cheating"; the requirement for a closed-book, proctored exam relates to how an individual prepares and studies for the examination.

When AAMRO was first established, it set up a *federal advisory board.* This advisory board included Dr. Joe Autry of SAMHSA, Mr. Loren Bush of the NRC, and Dr. Donna Smith at DOT. Members of AAMRO's federal advisory board told me that a proctored exam was essential and that *a non-proctored exam had no integrity or credibility.*

If SAMHSA is going to "approve" MROCC as an MRO certification board and include the MROs who have not been subject to a closed-book, proctored exam, SAMHSA will in one step eviscerate the professional credentialing integrity of MROs for all federal agencies. If DOT follows suit, it will undermine the legal defensibility of all of the drug tests done for DOT's operating administrations by MROs who are not well-credentialed.

By establishing a checklist approach to credentialing and "approving" the home study and certification courses, SAMHSA will open the door to a host of new "certification" agencies and will essentially make the standards for MRO credentialing lower than for a urine collector (who must at least do 5 mock collections).

If SAMHSA continues down this road, as I think it will, DOT and the public are in jeopardy of losing the most valuable asset in this program—the qualified independent Medical Review Officer. All I can state with certainty is that AAMRO is not going to lower its standards for its training program or credentialing process or abandon its proctored exam to meet SAMHSA's requirements.

AAMRO will continue to do what it has done for over 20 years: comprehensively train and empower the physician to be both a competent MRO and an independent medical expert in the area of drug testing and substance abuse control. I would take no pleasure in seeing MROCC not be approved, but I do see the irony here that AAMRO can and will stand alone as the standard of MRO competence and certification.

I would also note that the members of that disbanded federal advisory board asked me not to certify "MRO Assistants" because it would encourage the MRO to turn over the practice to the assistants. I agreed with that principle and kept my promise. AAMRO has never certified "assistants," although this has been big business for MROCC and others and has now created a second tier of problems for DOT and employers.

Who Approves SAMHSA?

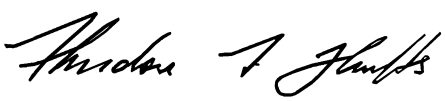
On a separate note, a physician who is not an MRO but who is familiar with all the history here asked the astute question: *"Who is credentialing or approving whom here?"* This is an important point that is often overlooked. MRO practice is not simply a technical issue of analytical chemistry or laboratory quality assurance. The scope and parameters of federal MRO practice are a function of public policy, jurisprudence and medicine. With all due respect, is it the intent of the administration or Congress—or for that matter, DOT—to allow SAMHSA to define federal employment policy or MRO professional practice? SAMHSA can and apparently does dictate what it deems as federal policy and employment law to other federal agencies and MROs who work for federal agencies, but they do not have to listen.

DOT needs to understand that if SAMHSA is now going to oversee the activities of MROs and establish "objective criteria" (which is policy) on which MRO certification is to be based, it would infer that DOT will relinquish its role in providing any guidance to MROs or employers in respect to MRO issues, just as it currently does with technical laboratory issues. Although it does in fact appear that DOT is now in need of re-establishing minimum standards of MRO credentialing, this SAMHSA approval process is not the ideal way to achieve it.

SAMHSA's interest in overseeing MROs will result in the wholesale wasting of a valuable asset, the devaluation of all MROs working in the DOT program, and the potential hobbling of a fundamental, independent, competent (and essentially cost-free) voice for all the stakeholders.

I hope I am not misunderstood: DOT and the government is well within its rights to approve or not approve of any aspect of MRO credentialing for federal mandatory drug testing programs, but it should be careful not to destroy or undermine the credentialing and value of MROs that already exist in these programs. I have and will continue to reach out and offer whatever I can to SAMHSA or DOT to make this program better. But this offer does not include not pointing out deficiencies, not raising technical concerns, or "going along to get along." If that was the real point of SAMHSA "approving" MRO certification boards, as it was explained to me, that obviously is not working out as planned.

Sincerely,



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