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NATIONAL MEDICAL REVIEW OFFICES, INC.

DEPT OF TRANSPORTATION

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March 21, 2000

Docket Clerk

Attn: Docket No: OST-99-6578 - 48

Department of Transportation

400 7th Street, SW., Room PL401

Washington, DC 20590

To Whom it May Concern:

Enclosed are three copies of the comments to Docket No: OST-99-6578, the NPRM for 49 CFR Part 40, procedures for Transportation Workplace Drug and Alcohol Testing Programs. These comments were also submitted electronically. If you require any further information, please contact Keith patten at 323-965-3103. Thank you.

Sincerely,


Keith W. Patten
Executive Vice President & COO



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**Responses to Department of Transportation, 49 CFR Part 40,
NPRM (Docket OST-99-6578) from
National Medical Review Offices, Inc. (NMRO)
March 21, 2000**

1. **Preamble.** The Department asked about the problems created when and if an MRO is required to be licensed in every/any state where a donor resides and the MRO is domiciled in another state. It is impractical, and illogical; to require a licensed MD or DO to have another license for every state that a drug test could be reviewed. Additionally, a donor may live in one state and have a verification interview performed while he/she is in another state (trucker on the road). Since DOT drug testing is not used for medical or clinical evaluation, the Department should take regulatory action to ensure that the MRO can accomplish his/her task (the identification of substance abusing individuals who are or could be placed in a safety sensitive position) without running afoul of a state law that regulates MD's performing their services in a clinical or diagnostic manner. DOT mandated testing is neither clinical nor diagnostic.

2. **Compliance with 49 CFR Part 40**

The proposed requirement for the service agent to have a signed contract with every employer, such contract including the compliance statement in 40.11, is unreasonable. As a service agent, we have many clients for whom we perform services who we do not have a contract with. If certification were indeed a requirement (has there been that many non-compliant service providers?), would it not be more appropriate for service agents to be registered and responsible to the Department for providing compliant services? Such registration could be along the lines of how minority owned businesses **certify** that they are in fact minority owned and **re-affirm** their status every year or so.

3. **40.45 (b) (2), the COC form.** There is no mention in this section of the requirement to have the MRO name and address on the form when used.
4. **40.47 (b), use of a non-DOT COC form.** The proposed requirement would be for the Laboratory or MRO to obtain an affidavit from the collector as to why a non-DOT form was used for a DOT collection. What is the purpose of this requirement? If a sample is collected and a non-DOT form was used, what difference does the reason make? If the result of the analysis is negative, does the Department suggest that the test be cancelled? If a sample is collected on an incorrect COC form and the MRO can get the donor to admit illegal use or abuse of a drug, does the Department suggest that the test again should be cancelled? Isn't the objective of the rule to detect and deter substance abuse among safety sensitive employees and not to determine who makes the fewest collection

mistakes? The requirement for an affidavit to support the incorrect form usage adds no credence to the fact that the wrong form was used. Should not the Departments position be that the mandated form should be used, but, when it is not, then the laboratory and MRO should make every attempt to determine that the collection was performed in a manner that is consistent with the spirit of the rule and that chain of custody for this collection is defensible. If those two conditions exist, then the test result should be treated as any other result determined from a sample properly documented.

5. **40.93 (1), validity testing.** The Department should consider the situation when a sample has zero **creatinine**. At this time, in order for a result to be reported as Substituted, the **creatinine** must be $\leq 5\text{mg/dl}$ and the **Sg** ≥ 1.001 or ≥ 1.020 . The Department should consider the situation when a sample has no **creatinine**, regardless of the specific gravity. The recent publication of **PD 37**, and the accompanying data, demonstrate that there were no instances of zero **creatinine** and any measure of specific gravity. Tap water could be substituted for urine and with nothing added to this sample, could pass for dilute and not substituted.
6. **40.121, (e), MRO training.** The concept of **MRO** certification is valid, however, the current **MRO** certification courses carry a three (3) year term. The Department should consider a **re-certification/qualification** term that agrees with those currently in place.
7. **40.101, MRO relationship with the Laboratory.** Although we take no exception with the requirement that there be or appear to be a conflict of interest between the **MRO** and a laboratory, it is interesting that the Department has never questioned the possible conflicts that exist between a laboratory and a collection site, or a **MRO** and a collection site. In a very many cases, laboratories own the collection sites (Patient Service Centers) where employers mandate the collection be performed and, many **MRO**'s are also the owners/administrators of Occupational Medical Clinics where collections are performed. In fact, many of these same **MRO**'s offer "bundled" services to their local clients and this bundled service consists of an analytical service provided by a laboratory which is priced depending upon the volume of business (samples) sent to the lab. Usually, a larger volume means a smaller price! If the Department feels the need to regulate the relationship between the Laboratory and the **MRO**, why has not the Department regulated the relationship between the collector and the lab or the collector and the **MRO**?

Apart from the obvious control or conflict of interest that may be an issue as to the performance of the service, why has not the Department questioned the fact that the collector knows the identity of the donor and therefore could pass this information to the laboratory (especially when the collection site is a lab owned

PSC)? It seems that much has been said about the relationship between the MRO and the lab but never about any other service provider relationship, which, on the face, could be at a greater risk from compromise of the system than any MRO/laboratory relationship. The Department should review its prohibition on laboratory/MRO relationships and, if required, then the Department should extend these prohibitions to other service providers.

8. **40.127, MRO review functions.** The requirement for the MRO to review all COC forms is admirable. However, what is the value to the Department and the employer when a negative drug test is cancelled due to the use of an improper COC form or a missing signature? If the error can be attributed to a “sin of omission instead of a sin of commission”, isn’t it in the best interests of the employer and the Department to verify and report the test as Negative?

The proposed requirement for the MRO to personally review at least 10% of the CCFs every quarter is unreasonable for an organization which is staffed and performs the Medical Review Officer services as their only business. NMRO has a staff of over 70 people, of which 7 are certified MRO’s, dedicated to performing MRO services. To suggest that the business of medical review of drug test results must be adjudicated by the Department is unreasonable. Again, the service agent should attest to the Department that they are compliant in the method and manner by which they provide service to covered employers. The Department should not attempt to regulate how a business performs its compliant services.

In this same vein, the proposed requirement for initialing the CCFs reviewed is akin to requiring the MROs to review the Hippocratic oath each day before they start work. It is an admirable idea but not realistic. NMRO reviews in excess of 1500 test results a day and to require our business to change our procedures and operations would not only be cumbersome but, an added expense to the regulated employers who use our services.

9. **40.157, 6 (d) (3), MRO reporting of test results.** The prohibition against an electronic signature on a negative test report is difficult to comprehend when a rubber stamp is authorized. What is the distinction in the Department’s mind between a rubber stamp and an electronic signature? It is our belief that an electronic signature is more controllable and auditable than an employee rubber-stamping hundreds of forms a day! The DHHS (FDA) allows electronic signatures for documents that could represent life and death depending upon the medical device or drug in question. Why can’t the DOT accept electronic signatures, if not for all results, certainly for verified negatives?

10. **40.201, cancellation of a test for an un-corrected correctable flaw. See #4 above.** The requirement to cancel a negative test result because of a missing signature, an incorrect SSN or the use of a non-DOT CCF seems to be

unreasonable. Does the Department believe that a transcription error by the donor or a forgotten signature by the collector should cause an otherwise negative donor to have to return to the collection facility and possibly lose a job opportunity due to a delay in reporting a valid result? Is this type of error by omission worth the added cost to the employer for having to pay for another test? For those negative donors who fall into this category, does the Department suggest that the results of the next drug test will be any different (i.e., positive) the next time around? Would not a more appropriate approach to these “correctable flaw” negatives be to verify the result as negative and move on?

The **un-corrected** “correctable flaw” positives deserve a higher degree of scrutiny but, none-the-less, every effort should be made to **verify** and report the result. A donor who has a valid medical explanation for a confirmed positive result, but who also happened to have a collector who failed to sign the CCF, should not be penalized because of the collector’s error. Only those confirmed and verified positive results that have **un-corrected** flaws should be considered as cancelable. In many instances, even when a flaw exists, the **MRO** is able to get the donor to admit illegal use. In these instances, is the Department requiring that the test be cancelled? The Department should take a more realistic approach to the adjudication of these samples that have a procedural flaw and consider an approach that recognizes that value of **verifying** and defending the first result in as many cases as possible.