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DATE: MARCH 16, 2000

SUBJECT: COMMENTS ON 49CFR PART 40

The following are comments per the request in the NPRM for 49CFR Part 40. We acknowledge and appreciate the efforts of the DOT employees who have contributed to the effort of revising this rule. It is our desire that our comments will assist in the revision of the final rule that will serve all involved parties of the DOT's Drug and Alcohol Testing Programs.

Sincerely,  
David S. Grauman, M.D., MRO  
Karen Manning, CSAPA



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The Department of Transportation has requested comments on proposed changes to 49(CFR Part 40). As a Third Party Administrator who has been involved in regulatory drug and alcohol testing since its inception (our FAA approval number is E-AL-000001-U), AAT has compiled a substantial expertise and experience in the application of drug testing to regulated industries, and is therefore pleased to be able to offer comments on the proposed changes.

Because the scope of these changes is so broad, the comments below are authored by different management groups within our company, and are divided into general subject areas, and those specific to MRO duties.

## I. GENERAL DUTIES AND FUNCTIONS

1. Regarding the use of a Non-DOT form for DOT collections; we agree that this should be a correctable error. This should also extend to the Breath Alcohol Form.
2. Regarding the viability of having a second test option in the event of collector error resulting in a rejected specimen; we believe that a second test should be allowed.
3. Regarding the requirement that each laboratory sign a certification that there exists no conflict of interest between the MRO and laboratory; it is our opinion that DOT has failed to explain or show what conflict of interest may exist. Further, this adds one more layer of red tape. It is our opinion that this will be a meaningless piece of paper.
4. Regarding the proposed requirement to force employees to drink fluids after a failed first attempt; we strongly disagree with this new regulation. The rule already provides a remedy if an employee ultimately cannot provide a specimen (e.g.: shy bladder review). It is our experience that this is such a rare occurrence, that a new rule to force a person to drink is unnecessary and adds an unneeded potentially negative confrontation between the collector and employee.
5. Regarding the issue of re-testing immediately if an employee's specimen result is dilute; it is our experience that many dilute specimens are the result of innocent over drinking of fluids by nervous employees prior to arrival at the collection site. In some cases

intentional over drinking occurs. We agree that a retest option would be beneficial. The “immediate” time frame should be established as “up to two weeks after receiving test results to allow employees to coordinate the recollection. Regarding the direct observation of the retest, we strongly disagree with this proposal. As noted above, the majority of dilute specimens are a result of over drinking prior to the test, not adding water to the specimen at the collection site. Thus, direct observation is meaningless. A more useful requirement would be that the employees be directly escorted to the collection site by the employer/supervisor. This would prevent dilution by over hydration.

6. Regarding the reduction of paperwork by the elimination of original copies of the drug testing form from the lab to the **MRO**'s; we agree that this would be beneficial to all parties.
7. Regarding Laboratory testing for **adulterants**; we strongly agree to laboratory testing of adulterated, substituted/diluted specimens. Since there are organized efforts to develop new and better **adulterants**, we encourage language that would enable and require laboratories to continually evaluate and update testing for **adulterants** in order to remain current with new **adulterants**.
8. Regarding adulterated, substituted, and dilute tests; we agree with DOT's proposal “First Option, do nothing beyond the procedure set forth in the regulation text, in which there would be two separate tests of the primary specimen before a finding of substitution or adulteration is made.”
9. Regarding the “stand-down” of employees pending a final **MRO** determination of a positive test; we agree with alternative #2. This would allow employers the option of stand-down and would allow them to better manage their liability associated with a safety sensitive function being performed by a potentially disabled employee. Regarding employee rights in this situation, we encourage that all consideration be given to the employee. In light of the fact that most **MRO** verification is completed relatively quickly, the impact to employers should not be too prohibitive even if full pay and benefits are continued until conclusion of the process. Regarding confidentiality, of course every effort should be required to safeguard personal privacy. However, the liability associated with continued performance of safety sensitive duties is too great to allow such duties to be continued pending the conclusions of the **MRO**'s review.
12. Regarding the proposed retest established by 40.183(d)(4); we agree that a retest under direct observation should be allowed in the event a split specimen is unavailable for testing.
13. Regarding the continued use of single specimen collections; we strongly believe that **RSPA** and **USCG** be required to utilize split-testing protocol. This will lead to more uniform collection protocols and thus fewer errors.
14. Regarding mandatory retraining of **BAT**'s who make a mistake resulting in the cancellation of a test; we believe retraining after one mistake is a costly and unnecessary step. We suggest retraining after 2 such mistakes.
15. Regarding the requirement for a third-party service agent to be responsible for reporting a continued performance of safety sensitive duties after having tested positive for drug test; we strongly disagree. The volume of tests and the number of separate company programs being administered by a typical third party agent precludes the

action suggested. Third party agents are not or should not be placed in the position of enforcement of either DOT or employer consequences for any employee who breaches the rules. Further, the DOT rule has consistently and carefully maintained the confidentiality of employee test results. To now propose that a third party should report “possible” violations opens a “Pandora’s Box” of liabilities. For example, what if the third party agent mistakenly “informs” of an infraction? It is contradictory that DOT would not allow an MRO assistant to inform an employer of a known positive test but would “require” a third party clerk to “inform” the DOT. And finally, suppose a DOT employee is involved in a serious accident. An investigation shows that the employee had a known positive test. Under the proposed rule, the third party could be held liable because it may have failed to make DOT aware of information it might (or might not) have had. In our opinion, this proposed rule has no merit.

16. Regarding the proposed Public Interest Exclusions (PEI’s); as a third party service provider, we are well aware of the potential problems DOT regulated companies can experience when they have associated themselves with incompetent and/or unscrupulous service providers. However, we believe that DOT is proposing a solution which shifts the primary responsibility for properly managed programs from the DOT and their regulated companies to third party providers. Unfortunately, third party providers do not have the authority to force a DOT company to maintain a compliant program. We believe instead that DOT should require every operating agency covered under the rule to pursue a policy of thorough company audits. Two agencies that currently do this are the FAA and FRA. It has been clearly demonstrated that a regulated company under FAA or FRA will not remain with an incompetent or unscrupulous third party service provider. Thus, the forces of our free market system would eliminate incompetent third party service providers through aggressive DOT enforcement of existing regulations. Unfortunately, most agencies covered under the rule do not take enforcement seriously. Thus, there is no incentive for a DOT company to seek out and pay for the best third party providers. DOT must realize that quality programs cost more money. If DOT agencies do not enforce the regulations imposed on their regulated companies, these companies will usually opt for cheaper programs which cut corners. Therefore, we encourage DOT to pursue a more active auditing of all modalities (similar to the FAA and FRA).

Notwithstanding the above, we also acknowledge that DOT agencies should be able to review/audit third-party providers in order to verify compliance. However, we believe that this should only be authorized as a part of an audit of an individual DOT company. To undergo an audit, as allowed in 40.363(b), that would include every record for every DOT company in the service agents files would place an unusually large burden on the small businesses providing these services. A service provider review combined with the individual company audits will provide the on-going history needed by DOT agencies.

Regarding the “alternative method, to achieve the objective”, we encourage the implementation of option #2. (e.g.: “as a condition of participation, all service agents would be required to self-certify that they provide all services as required by Part 40. Instead of issuing a PIE, the Department would decertify service agents that failed to carry out requirements properly.” As you know, this is very similar to the current FAA “approved consortium” policy process. This seems to work well. The information on acceptable providers could easily be provided to DOT-companies via the Internet and publications.

17. Regarding 40.11(d), statement of compliance requirement; we strongly disagree with

this requirement. In many cases DOT companies and third-party providers are forced to rely on services performed by independent medical clinics, laboratories and collection sites. These facilities are not under the direct contract of either the employer or the third party providers. In most cases these facilities are located in a remote site or location far removed from the DOT company's normal operation. We have experienced difficulty in persuading these facilities to even participate in the program. We expect that most, if not all, of these critical remote facilities will refuse to provide services if the extensive additional training, certification and general complications proposed by the rule go into effect. This will severely impact the ability of the DOT companies in our region to comply with the regulation. This poses a serious impediment to DOT company's compliance with (1) post accident testing (2) reasonable suspicion testing (3) 24 hour coverage requirements (4) pre-hire testing.

We do not have a perfect alternate proposal. We can feel confident that if this requirement is put into place, the DOT companies in Alaska will face tremendous increases in cost if a "certified compliant" provider must be dispatched from a metropolitan area to a remote site to perform routine collections that can be, and are currently being, provided by an independent clinic or lab. However, as a third-party provider subject to de-certification based on mistakes made by outside clinics/collectors, we will be forced to eliminate these remote clinics from our "umbrella" of services. This will place severe hardships on all DOT companies in this position. Perhaps a compromise solution would be to not count independent clinic/collectors mistakes against third-party providers. If this were clearly stated in the rule, we as third-party providers, would be able to continue to assist our DOT companies in obtaining testing in these difficult remote situations.

18. Regarding collector requirements 40.33;

1. Regarding the training of collectors; it is our opinion that self-instruction is not adequate. There are many collectors/collection sites who will not discipline themselves to self-train. This is really nothing more than the current situation. Training should be provided by certified trainers similar to the current BAT system.
2. We do not agree that retraining every two years is needed. Section 40.33 a(4)(5) already covers retraining when needed. The retraining of collectors every two years will create a severe impact on collectors in clinics/collection sites in remote or infrequently used facilities. It is our experience as third-party providers that these independent sites will not participate. It is simply not worth the time and expense for them to do so. However, their loss will greatly impact the overall DOT program.

19. Regarding 40.6 1 (f); we disagree with the intrusive provisions such as, removal of personal items in pockets, removal of boots, etc. These provisions alone are not effective if the intent is to discover adulterants. We believe the current rule provides adequate measures. Only a complete strip search would truly eliminate all tampering with the test. Since DOT clearly does not want to go that far, the inclusion of a partial strip search only causes increased resentment among honest employees while doing little to deter tampering by the dishonest ones. It is our opinion that anti-drug programs will never eliminate &drug use in the workplace. To attempt to achieve that goal would certainly lead to the abuse of the rights of too many honest citizens. Instead, we should all be pleased with the positive results of the DOT program thus far. Frankly, we would rather support a prohibition of over-the-counter adulterants than increased infringement of the privacy of working citizens.

## II. MRO SPECIFIC DUTIES AND FUNCTIONS

### 1) Training

We concur that formal training should be a requirement of physicians performing MRO duties. The proposed formal training every two years seems reasonable, but does not address the adequacy of such training. Two professional organizations already provide such training and certification, using nationally recognized standards of training, and requirement of such certification would insure that training was done adequately.

It is understood, however, that the DOT may wish to avoid any semblance of favoritism that might be implied by such endorsement. In that case, then at a minimum the required MRO training should qualify for Category I credit as defined by the American Medical Association for Continuing Medical Education; this would insure that training programs met nationally acceptable standards for medical education.

### 2) MRO Relationships

We are disturbed by the current trend to “distance” MRO services from the other functions of an anti-drug program or Service Provider. There have been several instances in which the MRO services provided by MRO service groups who have not had any close association with the other functions of a third party administrator have led to serious breaches in ethical function, such as the abusive use of “MRO assistants” where the employee was merely being “offered the opportunity” to speak with the MRO. It is our contention that this type of sterile, uninvolved MRO function renders unavailable many of the major MRO responsibilities delineated by the DOT. It is noted that the original definition of a Medical Review Officer is a “Licensed physician, knowledgeable in controlled substance abuse disorders” is retained, although the proposed rule clarifies the necessity for knowledge of laboratory analysis. Nonetheless, the intent clearly remains that the MRO must be able to interact in a meaningful way with employees who have developed chemical abuse disorders. Specifically, two operating administrations require the MRO to be involved in return to duty decisions, an involvement that is difficult or impossible to achieve if the MRO is a function totally separate from other aspects of the anti-drug program. It is extraordinarily difficult to perform these duties if the MRO is not integrated into the other functions of the Service Provider. It is agreed that MRO oversight of laboratory functions requires an “arm’s length” relationship between the MRO and the laboratory. However, total lack of involvement of the MRO from the testing process, company policy, collections and other Service Provider or company medical functions is neither appropriate nor desirable for several reasons, and should in no way be restricted.

We feel that the MRO has several functions where integrated involvement with the collection site and/or service provider or TPA are greatly in the interests of a successful program. Firstly, the MRO will frequently find him or herself in the position of assisting the employee with proceeding with an SAP evaluation and treatment. While in serving as the MRO for a large company the MRO would ordinarily leave this function to the Human Resources Department or management of that company, when serving as MRO for a small company, the MRO will frequently be intimately involved in these referrals due to lack of familiarity with the process by company management. This is especially true in those companies regulated by the FAA, where licensure under part 67 of the Federal Air Regulations is involved. In these cases, the MRO may also be asked to serve as the sponsor of the employee for return to duty requirements under FAR part 67. Secondly, the MRO by virtue of knowledge of substance abuse is in a unique position to guide both a company and its Service Provider in formulating rational company policy in those

instances where return to duty is an option, or where other testing under separate company policy is involved and must be **deconflicted** from testing under 49 CFR part 40. Thirdly, the **MRO** may well have other duties within a company's medical department, such as medical qualification exams, of which **MRO** duties are but one part. Fourthly, the **MRO** may well have the appropriate expertise to assure proper training and performance of collection site personnel, which may in any event be so integral with the functions of a Service Provider as to be inseparable. And, finally, there are no **MRO** duties which could present potential conflicts of interest between the **MRO** and Company or Service Provider that would make such distancing important.

While the current evolution of the "**MRO System**" precludes the *requirement* that the **MRO** have such a consultative role or any substantial involvement with other company or Service Provider functions, certainly greater integration of **MRO** functions should be strongly encouraged, and in no way restricted. It is clear that the **MRO** must be able to seek reimbursement for these additional **MRO** functions, such that it is perfectly appropriate that the **MRO** be employed as a manager within the service provider as a whole. Further restrictions on **MRO** ownership or management of a Service Provider would therefore be counterproductive in the extreme, as well as posing an arbitrary, unfair and severe economic hardship on those companies and providers who have been formed and continue to operate with the **MRO** as a part of the ownership and management structure of the Service Provider.

### 3) Licensure Issues

As noted above, it is our contention that significant **MRO** duties have been, and remain, clinical in nature. The fact that licensure in those states in which one wishes to provide clinical services is costly and cumbersome does not negate the fact that rendering a medical opinion requires such licensure. If the states are to be preempted in their licensing authority, then who is going to be responsible? The DOT needs to ask itself; does it really wish to place itself in the position of regulating and licensing physicians who are to serve as **MRO**'s? Does the rule wish to eliminate the provision that an **MRO** must be a "licensed physician"? The entire issue of "**telemedicine**" is under intense scrutiny by all state medical boards, who guard jealously their authority over physicians providing medical services within their state.

One simple solution is to have physicians enter into collaborative agreements with physicians who are licensed to practice in the states they wish to serve. This is already the established practice for most other areas of medicine, just as it is for lawyers wishing to provide services in states in which they have not been admitted to the Bar. Although it is convenient and lucrative to be able to provide nation-wide service without such agreements, there are many precedents in which similar activities have been judged illegal. It would seem that the DOT would much more wisely spend its resources on other aspects of this program, rather than initiating contentious relationships with state medical boards, since other solutions to the issue are available.