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SERVICES

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January 20, 2000

Docket Clerk
Attn: Docket No. OST-99-6578 - 7
Department of Transportation
400 7th Street, SW., Room PL401
Washington DC, 20590

DEPT. OF TRANSPORTATION
DOCKETS
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Dear Docket Clerk:

Enclosed are comments concerning the proposed changes in 49 CFR Part 40. This cover letter is for the purpose of making a general statement and also asking for clarification. The general statement concerns the practice of DOT of not being a certifying body. It is the opinion of OHSA that DOT should develop its own criteria for certification of MROs and SAPs. By allowing an outside certifying body be the pathway to certification the DOT is limiting itself to the perspective, model or practice of a particular group. This limits the availability of other qualified persons who decided to use a different model or practice.

While OHSA certainly supports the inclusion of the Personal Interest Exclusion there are some questions that concern us as a Service Agent. Questions about the PIE have been raised in other places but I would like to have clarification on the all or nothing nature of the proposed process. Will the Service Agent be able to defend itself when an employer has had noncompliance pointed out to them by the Service Agent but still has not complied. The problem I have with the proposed rule is that a noncompliance employer could affect all the contracts of a Service Agent when the Service Agent is doing all in its power to have all clients in compliance.

If there are questions concerning any of the comments by OHSA please feel free to contact me at 800-367-6472.

Sincerely,

Ben F. Padgett
Vice President of Operations

Service Agent Assurance Proposed § 40.11 includes new provisions that call for both regulated employers and their service agents to sign a contract provision committing them to compliance with Part 40 provisions.

OHSA supports this provision wholeheartedly. The difficulty, however, appears to be one of direction. It is our experience as a Service Agent that we are most often the one attempting to lead an employer through changes necessary for compliance. If we understand the proposed change, the employer is ultimately responsible for making certain the contract paragraph proposal is included in all contracts and that the Service Agent follows Part 40. Should the criteria not be met DOT would terminate the contract.

Would the contract termination hold true where a Service Agent has repeatedly notified a client of non-compliance along with an explanation of how to either return to compliance or, when that is no longer possible, make a good faith effort. It is clear that a contract makes an employer and a TPA partners in compliance but an employer audited by DOT and found out of compliance could effect the TPA negatively even though the TPA is doing all it can to keep its client in compliance. Since a Service Agent does not have authority to force a change, it is difficult to see how terminating a contract would be helpful to the employer or the Service Agent.

Perhaps there needs to be a certifying process for TPAs. Better still, a documented notification process could be stated in the DOT rules. A TPA upon discovering an employer is out of compliance, or may be out of compliance, would notify the employer in writing of the issue along with the rule stating the TPA-employer relationship. Following the notification the employer would have three months to bring their testing program into compliance. If successful the issue would simply be documented and filed. If the employer failed to correct the problem the TPA would again notify the employer in writing with an explanation of what is needed to bring the program back into compliance. The second notification would have a fifteen-day correction period. After that period of time if the employer had not corrected the problem the TPA would be required to notify the employer a third time with a copy to DOT.

Collector Training Consequently, the Department proposes in § 40.33 that collectors read and understand DOT rules and guidance concerning collections, demonstrate proficiency by completing three consecutive error-free trial collections, and receive retraining as needed.

First, there is some confusion concerning the number of error-free demonstration collections that must be completed. Is it three or five?

OHSA supports collectors being trained. At the same time there are some difficulties that the industry, as well as employers, will have to struggle with. For example, a post-accident collection situation where time is an element to be

considered. Getting any kind of proof of a collector's training may put one outside the testing time window. To not demand proof of training could result in a test failing to meet Part 40 and the employer-service agent contract could be terminated.

Another element is the employee turnover rate at the collector level in physician's offices, clinics and laboratories. In order to at least slow the turnover rate at this level of employment, higher wages will most likely have to be paid. This ups the cost of testing and pushes the employer to seek alternative means of testing, such as on-site or quick tests. With on-site testing being considered by DOT, higher collection costs could certainly translate into employers doing their quick tests and throwing away positive results.

At the present time, a TPA will **notify** the certified laboratory of a new collection site and request CCFs be supplied to the collection site. The laboratory then supplies the forms as requested. This would be one place for checking if collectors are properly trained. The laboratories could request documentation of collector training. However, I don't think this is something the laboratories should have to maintain.

Drug Testing Forms and Materials Should U.S. employers also be permitted to use these or other foreign-language versions of the forms? If this is allowed, additional questions may arise (e.g., should a foreign-language form be used only when both collector and employee understand the language?).

Because testing results carry such significant weight in the lives of employees and accuracy is the primary focus, OHSa believes that multi-language forms should be used only when the donor and collector both understand the language and beyond that only when the Medical Review Officer and donor both understand the language. Any kind of misinterpretation can be too costly to either the donor or employer or both. To add an element that could increase the risks does not reflect the spirit of determent.

It should also be noted that collection mistakes have been a constant means of testing problems and to add anything that could make mistakes more likely is counterproductive.

Electronic Records and Signatures The Department again seeks comment on the potential applications, advantages, risks, and safeguards for the use of electronic signatures and the greater use of electronic records in the DOT drug and alcohol testing program. For example, are there electronic "stamping" mechanisms we should permit for use with the CCF?

With the proposed changes in the Custody and Control Form the ability to scan and store CCFs is enhanced greatly. Storing these forms electronically is much more efficient than using paper forms stored in files. The ability to retrieve them

is also enhanced greatly. There is so much faxing of information throughout the industry that I can see no difference in using computer communications more directly.

The greatest threat to the electronic advantages would be for Service Agents and employers to fail to use proper backup procedures. A failed hard drive could spell information loss that would mean no retrieval was possible in the future. However, with proper backup procedures this is held to a minimum and probably represents no more threat than a building fire. In fact, where backup media is stored in fireproof vaults the threat would be less than with paper. The DOT could publish a backup procedure that anyone using electronic storage would have to follow.

It is obvious that electronic stamping of signatures could provide a way for some **MROs** to avoid involvement with the testing process where their signature could be affixed by anyone. However, for reporting from electronically stored and retrieved documents it would save valuable time and expensive space.

It is conceivable that the DOT could actually be an industry wide database via the Internet. Employers and/or **TPAs** could use the DOT as a backup to their own database programs.

Collection Process (a) If an employee does not show up at the collection site at the scheduled time, contact the **DER** to determine the appropriate interval within which the employer has determined the employee is authorized to arrive. If the employee's arrival is delayed beyond that time, you must notify the **DER** that the employee is a "no show."

This provision needs to be reworded to recognize that most collections are done without an appointment and the collector will not know if the donor has arrived on time or not. **OHSA** has begun encouraging employers to use authorization sheets defining the service required and the time the employee was notified of testing. While most employers do not use such a form it could be most helpful in the time issue as well as the type of testing to be completed.

There are downsides to authorization forms, for example, when the collectors do not pay attention to the document and simply imagine what is marked. Also, when authorization forms are agreed upon and employees show up for testing without a form. Some employer protocols state the testing process should not continue without the form. In such cases a forgotten or lost form delays the testing process until one can be secured by the employee.

(b) Make sure that, when the employee enters the collection site, you begin the testing process without delay. For example, you must not wait because the employee says he or she is not ready or is unable to urinate or because an authorized employer or employee representative is delayed in arriving.

There needs to be further clarification on this rule. Is it saying that an employee presenting for testing must be taken prior to other patients seeing a physician? If so, even though it would be a good process, there is little chance it will be followed. When collections are done in general practice clinics or **offices** they **often** have to be in line along with everyone else. A few clinics have in place a pathway around this wait process but most do not. Many physician **offices** and clinics are not supportive of the urine drug collection process in the first place and this would result in a significant number refusing to provide collection services.

OHSA's experience in this area has been that even when a clinic has a procedure in place for no-wait collections for drug screens it still does not happen. And as mentioned earlier there are many occasions when the paper glitches stop the process altogether.

The proposed rule would stipulate that in the event an employee, after presenting an insufficient amount of urine, refuses to drink fluids as directed by the collector, the collector is to stop the collection proceedings. A failure to drink as directed would constitute a refusal to test (§§ 40.191(a)(5) and 40.193(b)(2)).

This is an excellent criterion. It is my opinion that a donor should be instructed by the collector that he or she must fully cooperate with the testing process, such as drinking water as directed, or the test will end and be remarked a refusal to test. If the donor continues to refuse to cooperate the testing should be stopped at that point. Too often employees have used the three hour rule as a means of getting a paid three hours off the job.

Blind Specimens

OHSA believes that blind samples serve a good checks and balance but would certainly support a modification that could lower the cost of testing. This may be a spot that could offset collector training requirement costs.

MRO Training and Responsibilities MROs would have to take a training course every two years or certify that they have reviewed and understand Part 40 and applicable DOT agency regulations and guidance.

This change would increase the cost of testing to a prohibitive level unless the DOT is willing to allow other knowledgeable professions to provide **MRO** services, Perhaps certifying **MROs** have reviewed and understand Part 40 would be an excellent idea but retraining costs would be passed on in higher **MRO** charges.

The DOT could send a questionnaire to all **MROs** every two years with questions reflecting the **difficulties** reported in testing and changes in Part 40. In this manner **MROs** would be encouraged to stay abreast of the changes in regulations and in interpretation challenges.

Recently, we have learned of some concerns that some state medical licensing agencies may believe that out-of-state **MROs** who are not licensed to practice in the state may not be authorized to perform **MRO** functions with respect to employees located in the state. The Department is interested in learning whether this is a significant issue, and if so whether the issue poses a serious obstacle to the performance of **MRO** functions in a national safety program. If there is such a problem, should the Department take regulatory action to address it? If so, what action would be appropriate?

MROs, other than those who may actually provide services as an employee, are not treating employees who test positive on urine drug screens. To limit a **MRO** to respond to positive results in only the states he or she is licensed would totally cripple the testing program. For employers with nationwide divisions it would mean at the very least involving more than one physician. The expense of testing increases and the risk of mistakes rises as well. Since this is a Federal program it seems it would override any state licensing criteria. If regulatory action should be taken it could be something like the preamble of the present testing program that states state laws do not govern the testing.

Third, the Department has viewed an adulterated or substituted specimen as more closely analogous to a refusal to test than to a positive test.

It is the opinion of **OHSA** that an adulterated or substituted specimen should be treated as a refusal to test rather than a positive. However, the same requirements of a positive result should be demanded. Particularly, with the general lack of knowledge concerning contaminate deterioration, and the large number of possible contaminants, it seems only logical that it would continue to be a refusal. A positive test, in our opinion, is one that has been tested and confirmed as positive at the laboratory and then given a final result of positive by a **MRO**. One concern of **OHSA** on this matter is that if an exception to what a positive result means is made for one or more contaminants the door is opened to other exceptions. The consequence could be that the meaning of a positive result would become increasingly confusing with a greater number of legal challenges.

SAPs

There is no reason I can see that **SAPs** need quantification of drugs. It really does not have anything to do with addiction and there are other more historically definitive criteria that can be used in assessment.

The proposal to have **pre-employment** positive results assessed is excellent but will be **difficult** to enforce. Will there be a database somewhere where results will be kept, Often, **MROs** are unable to contact **pre-employment** positives because there is no one to instruct the donor to contact the **MRO**. How will a future employer know an individual has tested positive?

There are several questionable elements to the SAP qualifications process. To have the National Commission for Certifying Agencies (NCCA) be the pathway to certification means that any certifying body seeking this certification will have to spend at least \$3,000 annually. To use the Drug Abuse Counselors Certification Commission (NAADAC) and the International Certification Reciprocity Consortium / Alcohol & Other Drug Abuse (ICRC) as the standards leaves out other highly qualified individuals who have traveled a different professional pathway. This is true with the DOTs definition concerning Certified Employee Assistance Program providers.

To use myself as an example, rather than seeking NAADAC, ICRC or EAPA certification my pathway has been to become a Clinical Member of the National Institute of Business and Industrial Chaplains (NIBIC) and certified as a Certified Pastoral Addictions Counselor with the National Board of Addiction Examiners (NBAE) because these are pastoral organizations. In addition to a Master of Divinity Degree from Candler School of Theology, Emory University, I have six clinical quarters of training with extensive experience in alcohol and drug treatment and employee assistance programs. NIBIC has qualified men and women, all ordained, in all types of workplace settings. NIBIC has never seen the need to certify its members because each has had to meet a rigorous qualification process in order to qualify for membership. Some examples of EAPs directed by NIBIC Clinical Members is R. J. Reynolds, Republic Industries, race tracks throughout the nation, and, of course, American Family Care and its sister company OHSa that employes me. The NBAE is used by the Department of Army, the Department of the Air Force, the United States Coast Guard, and the State of California in certification qualifications for alcohol and drug treatment and family violence programs. The problem with accreditation programs is they are exclusive rather than inclusive.

Perhaps a combination of processes could be used where individuals can apply for SAP certification through the DOT and certifying bodies through the proposed rules.

Certification Suggestion

It is the suggestion of OHSa that the DOT certify MROs and SAPs rather than relying upon outside certifying bodies. The DOT could charge an annual fee of \$100.00 for physicians and \$50.00 for other professionals and cover the cost of qualified professional persons being on DOT staff. These persons would have the responsibility of developing certification criteria and training.