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Mr. Walt Vogl, PhD
Drug Testing Section, Division
of Workplace Programs, CSAP
5600 Fishers Lane
Rockwall II, Suite 815
Rockville, MD 20857

HHS Docket # 04-7984

Dear Dr. Vogl:

Following are the comments of the Drug & Alcohol Testing Industry Association (DATIA) on the Proposed Mandatory Guidelines for Federal Workplace Drug Testing Programs. DATIA is a 1,200-member national trade association representing the full spectrum of drug and alcohol testing service agents including laboratories, collection sites, C/TPAs, BATs, MROs, SAPs, employers, and testing device manufacturers. DATIA's mission includes working closely with key policy makers in Federal Agencies and in Congress to ensure that the interests of the industry are heard and taken into account when changes in drug and alcohol testing rules are proposed. DATIA works to ensure that these changes foster rather than hinder the industry's growth. DATIA further works to educate the industry on current standards of service and regulatory policies and procedures. DATIA's comments on behalf of its constituency are based upon input from DATIA's members, Legislative & Regulatory Committee, and Board of Directors.

DATIA wishes to commend the Department on their efforts to update the guidelines to include new technologies that are widely used in the private sector. The inclusion of alternative testing methods is much needed and appreciated by professionals in the drug and alcohol testing industry. DATIA and its members are concerned, however, that many of the requirements established in the proposed mandatory guidelines will negate the positive benefits of using these new technologies and will be unimplementable as written. While we have identified many areas of concern, our comments focus on the top 10 major problems found.

Our comments on the proposed mandatory guidelines follow. Please feel free to contact me if you would like to further discuss any of the following comments.

Sincerely,

Laura E. Shelton

Laura Shelton
Executive Director

Need for DOT Collaboration

DATIA suggests that the Department incorporate the Department of Transportation's (DOT) CFR 49 Part 40 regulations as they relate to collections, shy bladder, etc., into the proposed mandatory guidelines. Much input from the DOT, industry, and employers were used to compile those regulations, and they have proven to be extremely effective. The majority of collectors that will collect specimens for federal testing also collect specimens for DOT mandated drug testing, and use the DOT collection procedures when performing testing for the private sector. Although the differences between procedures are subtle, they do exist. For example, in a shy bladder collection in the proposed guidelines, collectors are directed to give the donor "a reasonable amount of liquid". Also, 45 mL is required for a split, but then the donor need only provide 30 mL if there is a shy bladder. The DOT regulations are very specific on this (i.e. 40 oz. In 3 hours) and the Department should follow the same guidelines. Because of the strong regulatory relationship between the mandatory guidelines and DOT drug testing regulations, it makes sense to have consistency. Without this consistency, confusion will result and errors will occur.

Requirements Inappropriately Applied Across the Board

DATIA suggests that the Department review the collection procedures to make sure that they are applicable to each type of specimen. It appears that a cookie-cutter approach was taken and some of the requirements do not apply to each type of specimen. For example, why does a donor need to empty and display the contents of his/her pockets for a sweat patch application? Why is there a need for a donor providing an oral fluid collection to remove his/her outer garments? The donor will question all of these, and there is no reason that we can see to provide to the donor. In addition, steps needed for certain types of specimens are omitted. For example, what steps should the collector take to protect the privacy of the donor when a sweat patch needs to be applied and this requires the removal of clothing? For these reasons, DATIA asks that the collection procedures be applicable to the type of specimen being collected.

Subpart E, §5.5 What are the privacy requirements when collecting a hair sample? Subpart H, §8.2 What procedure is used to collect a head hair specimen?

The rationale to allow only head hair collection is not apparent. If the Department sees no privacy concern with applying a sweat patch to the back or arm, then why is there a privacy concern with collections hair samples from these areas? Clearly, collecting a hair specimen from an arm or underarm is less invasive than a direct observation urine specimen collection. A donor who does not want to submit to a hair test need only shave his head. DATIA suggests that the Department revise this section to allow hair collection from other areas of the body, and include wording to prohibit collection from areas such as the pubic region.

Subpart E, §5.6 What are the privacy requirements when collecting an oral fluid sample? Subpart H, §8.3 What procedure is used to collect an oral fluid specimen?

DATIA sees two problems with the proposed guidelines for oral fluid testing. First is the requirement that the donor "spit" into a vial. The majority of oral fluid testing products currently being used involve the use of a collection pad that is placed in the donor's mouth. This collection pad is then used to transfer the oral fluid into the vials to be sent for testing. This type of collection is much more professional, streamlined, and will not result in any "mis-spits" that don't end up in the vial.

Secondly, the requirement to perform a urine collection with every oral fluid collection negates the reason why so many employers prefer oral fluid testing. The collection process is less invasive and can be performed virtually anywhere, whereas a urine collection requires the use of a restroom. This is what makes oral fluid testing so useful for instances such as post-accident testing. In addition, oral fluid testing is the best means to test for recent drug use since oral fluid testing can detect use before urine and hair testing.

Subpart F, §6.1 What form is used for collection a specimen?

CCFs for alternative specimens have not been developed, and we anticipate that the Department plans to do this concurrently with development of the final rule. When will the public have the chance to comment on proposed forms, if not in the proposal? Does the Department contemplate a supplemental proposal for the forms?

The Department's rationale for requiring a different type of form for each type of specimen is not articulated. This will confuse the collection process, make more paperwork errors likely, and will add to information collection burdens. DATIA suggests having a single, comprehensive CCF with, for example, a box to check to indicate the type of specimen collected.

Moreover, to say that a separate form will be developed in the future with the assistance of each industry working group is a sign that this section requires much additional work. The current CCF was developed through a joint Department-DOT effort. There should be a commitment by the Department to work with DOT and other concerned Federal agencies, as well as industry groups, in further development of the CCF.

Lastly, nothing was mentioned to address electronic forms. Many other agencies have moved to electronic forms and the Department should move toward allowing a paperless CCF to be generated at the collection site and travel ahead to the laboratory and other places (e.g., MRO) that need collection notification. Technology exists that can solve the "paper chase" issue. A paperless CCF can become a reliable part of drug testing, and it is recommended that the Department develop policy and procedures to allow for an electronic CCF.

Subpart H, §8.6 What are the responsibilities of a federal agency that uses a collection site?
Subpart L, §12.8 What are the responsibilities of a federal agency that wishes to conduct POCT?
Subpart L, §12.10 What are the inspection requirements for a federal agency wishing to use a POCT?

The proposal for federal agencies to conduct semi-annual inspections of collection sites that it uses will be an enormous burden and an unrealistic requirement. What about "collection sites" that are set up temporarily on-site? How can they be inspected after the fact? Who will inspect the sites and what training will they have received? What must the inspection include? What happens if a site does not pass the inspection? Will the collection site need to pay a fee for the inspection? The goal behind the inspections is good, however, it is not feasible. It also appears that this section of the proposed guidelines was not thoroughly worked out. We suggest that this requirement be removed until these questions can be adequately researched and addressed.

DATIA also feels that inspections of thousands of POCT sites are also unrealistic. The Department states that is including POCT in the mandatory guidelines since "Employees of Federal agencies are

in some cases located in remote areas of the country...or overseas...They are often in locations with few employees..." And yet, the Department is requiring the Federal agencies to conduct periodic inspections of the POCT sites. The reasons above that outline the problems with inspections of collection sites also apply to the inspection of POCT sites. As such, DATIA suggests that this requirement also be removed entirely.

If monitoring of the facilities and their protocols is deemed necessary, this could be done in other ways including submission of Standard Operating Procedures, training and mock test documentation for POCT testers, and training and mock collection documentation for collectors testers to the Department or Federal agencies.

Subpart L, §12.16 What are the requirements to be a POCT tester?

DATIA does not agree that the training requirements to perform a POCT should be less stringent than those for the person collecting the specimen. The person actually performing the test and reading the results, if anything, should have more stringent training requirements. If not properly trained, a non-negative result could be read as negative, putting an impaired safety-sensitive employer back into his/her safety-sensitive duties. DATIA recommends that POCT testers be required to have their mock tests monitored by a qualified person, to have their knowledge and performance verified, and to maintain documentation of their training and mock collections. In addition, DATIA strongly feels that this sections needs to include wording that if the POCT tester is also collecting the specimen, that he/she must also meet the collector requirements in §4.1.

Subpart L, §12.19 What are the quality control requirements when conducting POCTs?

DATIA does not agree that quality control testing should be performed each day. Rather, each lot should be tested by the manufacturer before shipment and by the POCT site before placing the POCTs into use. If there is a problem with a device, there will likely be a problem with that whole lot. By requiring daily testing rather than lot testing, you risk the possibility of not testing a damaged lot. Since each test device is separate from one another, there is no added benefit in requiring daily quality control testing in addition to testing each lot. In addition, each device comes with an expiration date and storage instructions. POCT sites should be held responsible for ensuring these storage guidelines are adhered to and that no devices are past their expiration date.

Secondly, it is not addressed whether the quality control testing that is performed is positive for each drug class that the device tests for. If the purpose of the quality control is to ensure the kits work, wouldn't each device need to test presumptive positive for all drug classes.

Lastly, the requirement for each tester to run quality control testing is redundant. It appears that this requirement is to test the tester, not the device. If training of the testers is required, isn't this additional testing just another expense? The tester has received training, and if these training requirements are made more stringent, (see above comments) there will not be a need for the tester to perform "mock tests" on a daily basis.

Subpart L, §12.26 What type of relationship is prohibited between a manufacturer of a POCT device or a POCT operation and an MRO?

POCT operations should not be prohibited from having a relationship with an MRO. Most occupational medicine clinics, wellness centers, consortia, third party administrators, etc., provide

specimen collections, point of collection testing, and MRO services. Under these new guidelines, these businesses will be forced out of drug testing for federal workplace programs. In addition, what about the organizations required to perform drug testing under these guidelines who have their own medical director/MRO on staff? None of these organizations will be able to conduct POCT testing, unless they fire their medical director/MRO or contract the testing out to a third party. Both options place an unnecessary burden on the organization. DATIA does not see any valid reasons or positive effects for prohibiting MROs from being an employee of or having a financial interest in a POCT operation or device. No positive tests are reported from the POCT operation to the MRO since all non-negatives must go through traditional laboratory testing. Once a specimen has been found to be non-negative, the procedures follow those for traditional urine specimen lab-based drug testing, which do not prohibit an MRO from being an employee of or having a financial interest in a collection facility. POCT testing should not be regarded as laboratory testing, but rather as a form of screening out negative specimens at the collection facility from those being sent to the laboratory.

Subpart M, Instrumented Initial Test Facility (IITF)

DATIA does not understand the reasoning behind the addition of these new testing facilities. The use of an IITF necessarily involves a further transmittal of a specimen and associated paperwork for non-negative specimens (i.e., collection site to IITF to laboratory for confirmation testing to MRO). The Department has not addressed the potential problem of additional administrative error, chain of custody problems, or loss of specimens or paperwork created by introducing this additional step. In addition, the Department has been careful, under the current rules, not to permit or encourage reporting of negative results to an employer before non-negative results, since employers and other employees could make inferences about screening test results solely from the timing of the reports. Adding a separate step for the IITF-laboratory transfer makes preventing such inferences all the harder.

Another problem associated with these new facilities is the confusion that will be created involving the use of "SAMHSA Certified." Currently, testing providers and employers know that this refers to the few laboratories that have gone through the extra steps to be approved through the National Laboratory Certification Program. If you add in another type of facility that will be SAMHSA certified, confusion will result and unknowing employers, and service providers will find out the hard way that they did not send the specimen to a SAMHSA certified laboratory as expected. The DOT and many state laws require that drug testing specimens be sent to a SAMHSA certified laboratory for testing, and the Department needs to consider this when proposing new types of facilities for it to certify.

DATIA recommends that the Department further research the issues involved in creating this new type of testing facility before moving forward with this section of the proposed guidelines.