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Center for Substance Abuse Prevention (CSAP)
SAMHSA
1 Choke Cherry Road
Room 7-1045
Rockville, MD 20850
Re: Mandatory Guidelines for Federal Workplace
Drug Testing Programs - Oral Fluids
Docket No. SAMHSA-2015-2

Following are the comments of the Drug & Alcohol Testing Industry Association (DATIA) on the SAMHSA proposed mandatory guidelines to allow federal agencies to collect and test oral fluid specimens in their workplace drug testing programs (OFMG). DATIA is a 1,500+-member industry trade association representing the full spectrum of drug and alcohol testing providers 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, and provide for safe and effective drug free workplaces. 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 supports initiatives to promote drug free workplaces thereby increasing workplace safety, and we applaud SAMHSA for promulgating these proposed guidelines allowing for the collection and testing of oral fluid specimens. By inherently being a direct observed collection, the chance of adulteration or substitution of oral fluid specimens is very slim. Given the proliferation of adulteration products, this characteristic of oral fluid specimens is seen as an advantage. In addition, oral fluid specimen testing allows for the detection of drugs consumed quicker than in urine, which only allows for detection after the drug has been metabolized by the body. Therefore, specifically in post-accident testing, oral fluid testing can possibly be a better determination.

In regards to the OFMG, DATIA is in full support of the provisions and procedures within the OFMG. Throughout the guidelines, SAMHSA specifically asked for comments regarding certain issues. DATIA's comments on these are below.

- Split Specimen Collections – DATIA does not believe that serial collection of specimens, with the second specimen collected within two minutes of the first specimen, constitutes a split specimen or should be allowed. Much of the testing performed under HHS guidelines is performed by the Department of Transportation (DOT). DOT must follow strict regulations as a result of the Omnibus Transportation Employee Testing Act of 1991 and U.S.C. 313 section (c) (5) states "provide that each specimen be subdivided, secured, and labeled in the presence of the tested individual and that a part of the specimen be retained in a secure manner to prevent the possibility of tampering, so that if the individual's confirmation test results are positive the individual has an opportunity to have the retained part tested by a 2d confirmation test done independently at another certified laboratory if the individual requests the 2d confirmation test not later than 3 days after being advised of the results of the first confirmation test;". Therefore, we believe that oral fluid specimen collection within the HHS guidelines should require that enough specimen be collected at one time to be divided in front of the donor to create a true split specimen that will be acceptable for DOT testing, http://www.transportation.gov/sites/dot.dev/files/docs/199111028_Omnibus_Act.pdf

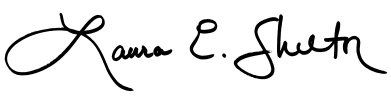
- List of FDA-Cleared Oral Fluid Collection Devices – DATIA supports having HHS publish a list of allowable (FDA-cleared) oral fluid collection devices. This is consistent with the currently published lists of SAMHSA approved laboratories and NHTSA approved alcohol testing devices, and will provide a clear and concise reference for all involved in the drug testing process to ensure compliance.

- MRO Recertification CEUs – DATIA does not support requiring recertification CEUs within the OFMG. SAMHSA already has established and effective procedures to approve MRO certification organizations for MROs performing such duties for federal drug testing programs. Each of these certification programs has their own training requirements for recertification so to add such a requirement to the OFMG would be redundant.

- Validity Testing, Cutoff Concentrations, Performance Requirements – DATIA defers comments on the scientific levels for these areas of the OFMG to the many laboratories that currently perform oral fluid testing. In addition, a number of these laboratories have participated in studies through the Drug Testing Advisory Board where data has been submitted and reviewed by SAMHSA. In determining the final scientific levels, DATIA feels that it is important to set the levels to maximize safety while also making the process for laboratories and MROs effective and efficient. In addition, the final cutoff level criteria needs to be set to ensure that the criteria is acceptable to be implemented by the DOT based on their regulatory confines (i.e. remove the possibility of passive exposure for positive results in oral fluid THC cutoff levels) that are required to follow these standards if they wish to adopt oral fluids into their testing programs.

DATIA thanks SAMHSA for the opportunity to provide comments on the OFMG. Please feel free to contact me if you would like to further discuss any of the preceding comments.

Sincerely,



Laura Shelton
Executive Director