From: Collins, Jennifer [mailto:jcollins@medtox.com]
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Subject: RIN 1219-AB41

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Comments regarding the Mine Safety and Health Administration proposed rule for alcohol and drug testing (30CFR parts 56, 57 and 66)

Inclusion of additional prescription medications in the proposed test panel

While it is recognized that misuse and abuse of prescription medications is a growing problem in the US, incorporation of these compounds into a workplace drug testing program adds a significant level of complexity to the laboratory testing and MRO review processes and should be embarked upon only after very careful consideration and evaluation of relevant data. In that regard, I submit the following comments:

1. While laboratory testing can identify use of the indicated prohibited substances, the value of a urine level in determining whether the individual is using the drug in manner consistent with a prescription is dubious at best. Likewise, the ability of the MRO to ascertain whether the individual is using the drug as prescribed will be limited. MRO data presented at the last two DTAB meetings shows that the majority of laboratory positives for prescription medications are reversed by MRO's (75 – 85%). Since this testing will add cost to the testing process, there may be limited value to adding these compounds to the test panel.

2. Laboratory Issues
   Cost: Adding compounds adds cost to the laboratory process and those costs will be borne by both the laboratories and the employers. The additional confirmatory testing that will be generated by the addition of these prescription medications impacts laboratory workflow and instrumentation requirements. The added costs both to laboratories and employers must be weighed against the benefits/value.

   Laboratory Capabilities – Not all SAMHSA laboratories participate in the CAP-FUDT program; there may be a limited number of laboratories that meet both certification criteria and provide sufficiently comprehensive panels to meet the requirements of the proposed rule.

   Laboratory test panels; included compounds. If additional drug classes are added, the rule should specify compounds that must be included in the confirmation test. Current confirmation panels for these prescription medications vary significantly from lab to lab in terms of the scope of compounds included. A voluntary survey of currently certified laboratories may provide sufficient information to make determinations regarding cutoffs and test panels.

3. CAP certification: the use certification by the College of American Pathologists is the best option to ensure that methodologies for the additional classes of compounds are subject to the appropriate level of review by the inspection process and monitoring by participation in the required performance testing (PT). The proposed rule should specify that CAP-FUDT certification is required and that the laboratory must demonstrate that they have included all of the proposed compounds on their list of provided services to the College to ensure that all of the tests have been reviewed during an on-site CAP inspection.

4. I disagree with the modification of the alcohol level requiring action from that used by the DOT (0.020) to 0.040. There is a significant body of literature demonstrating a relationship between alcohol levels and physiological and cognitive effects at levels well below those utilized in state dui/dwi statutes. Realistically, a breathalyzer result of > 0.020 could indicate alcohol consumption within the previous hour; I would argue that an individual with measurable alcohol above a 0.020 threshold could pose a safety risk. The DOT approach with tiered actions based on alcohol level seems to me to be a more prudent approach.

Respectfully submitted,
Dr. Jennifer A. Collins
Director of Forensic Toxicology
MEDTOX Laboratories, Inc
St. Paul, MN