A bold voice for transportation workers

June 6, 2022

Miriam E. Delphin-Rittmon
Assistant Secretary for Mental Health and Substance Use
Substance Abuse and Mental Health Services Administration
5600 Fishers Lane
Rockville, MD 20857

RE: Mandatory Guidelines for Federal Workplace Drug Testing Programs
Docket: SAMHSA-2022-0001 and SAMHSA-2022-0002

Ms. Delphin-Rittmon,

On behalf of the Transportation Trades Department, AFL-CIO (TTD), I am pleased to respond to the U.S. Department of Health and Human Services' (HHS) notice regarding the Mandatory Guidelines for Federal Workplace Drug Testing Programs. TTD consists of 37 affiliate unions representing workers across all modes of transportation.[1]

The Mandatory Guidelines provide the scientific and technical standards for workplace drug testing for over 12 million federal employees and transportation workers in the public and private sector.[2] The proposed Mandatory Guidelines would allow HHS to add and remove drug analytes and modify cutoffs without public notice or comment. The proposed guidelines also would change the definition of a substituted specimen to include certain specimens that are currently reported as "invalid." Additionally, the proposal would redefine refusals to include failing to complete pre-employment testing. Lastly, the guidelines would hold that ingestion of food products containing a drug is not an acceptable medical explanation for a positive drug test.

[1] Attached is a list of TTD's 37 affiliated unions.
[2] https://www.transportation.gov/odapc/employee

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TTD recognizes the good faith effort of HHS to prevent drug use from impairing employees on the job; however as discussed below, a number of the issues in the proposal raise legal, procedural, and substantive concerns that we urge the Department to reconsider and withdraw. TTD believes that some provisions in the proposed guidelines would not protect the public and undermine long standing employees rights. We concur with the position offered by our affiliated union, the Air Line Pilots Association (ALPA), in their comments filed in this docket.

TTD represents many of the employees subject to the Department of Transportation's (DOT) drug testing program, and we understand that DOT is only required to adopt the portions of the Mandatory Guidelines that establish scientific and technical standards, which primarily address the specific parameters of the drug testing panel. While we urge HHS to withdraw the problematic provisions in these proposed guidelines, if HHS moves forward to adopt the guidelines as proposed, DOT should not adopt such provisions that are unnecessary and contrary to the needs of the transportation workforce.

Public Comment and Administrative Procedures

The history of drug testing programs consistently shows that robust public participation is a key factor in creating good policy and regulation. This is particularly applicable to drug testing programs, which can have drastic consequences for workers' careers and livelihoods. Providing an opportunity for public comment on all changes to drug testing panels is the bare minimum requirement to ensure that workers are adequately informed of proposed changes and have an opportunity to make their voices heard. Significantly, the drug testing panel has been changed, consistent with the Administrative Procedure Act (APA), based on comments and additional scientific input gathered during public comment periods, specifically regarding validity testing, laboratory procedures, and ensuring that studies adequately represent women. Given the valuable information and feedback generated from the public and scientific community, there is no compelling reason to forgo this input.

The Department's argument that eliminating comment periods will enable a nimbler response to technology and scientific advances does not withstand scrutiny. Compared to the amount of time it takes to determine the reliability and scientific validity of potential revisions to the drug testing panel, a reasonable public comment period does not represent a significant delay. Further, the comment period ensures that there is scientific evidence and consensus to support metabolites, biomarkers, cutoffs, and other testing parameters. Well-informed regulatory policy should not be sacrificed at the feet of expediency. Removing the opportunity for public comment would remove the logic that new testing parameters are valid.

In the notice, HHS claimed that the Administrative Procedures Act exceptions allowed for the Department to make changes to the drug testing panel without public comment, and TTD firmly rejects this notion. The Mandatory Guidelines have applicability far too wide – covering millions of workers – to be subject to a narrow exemption meant to cover personnel matters relating exclusively to Federal employees.

The Omnibus Transportation Employee Testing Act of 1991 requires DOT to establish drug and alcohol testing standards by adopting HHS scientific and technical guidelines and then promulgating regulations applicable to the transportation workforce. However, when DOT publishes notice that it is adopting HHS's scientific and technical guidelines, DOT does not have the authority to modify the scientific and technical standards. This means that employees under DOT-regulated drug test programs only have a meaningful opportunity to comment on drug testing panels through HHS notices, making it even more important that the public is able to comment on changes proposed by HHS. Speed alone is not a sufficient justification to abandon public notification due process requirements. Consistent with ALPA's submission, TTD maintains that HHS is legally required to publish any changes to the Mandatory Guidelines, including changes to the drug testing panel, in the Federal Register with sufficient opportunity for public comment.

Validity Testing and Substitution

TTD opposes redefining which specimens are considered "substituted" during laboratory tests. Currently, a specimen that contains an unidentified element(s) or purportedly does not conform to the normal characteristics for human urine is immediately recollected, and this solution is sufficient. There are situations in which a legitimate sample may be reported as outside of the standards for human specimens, and current procedure allows for these samples to be declared "invalid" rather than "substituted." A finding that an employee has submitted a substituted specimen can have the same adverse consequences as a positive drug test result, and that HHS should ensure that it is impossible for a legitimate, unaltered sample to be found to be substituted under its rules and any proposed changes to them. It is wholly unacceptable for an individual who submits a legitimate, unaltered specimen to be found to have "substituted" that specimen and, accordingly, deemed a rule violator. Again, we believe that the current procedure regarding substituted and invalid tests fully meet the Department's goals, and the proposal to change it would only create risk of significant employee harm.

Pre-Employment Testing

Under HHS's proposal, an individual who fails to report for a pre-employment drug test would be reported as refusing to take the drug test, which can have the same consequences as a positive drug test. TTD believes that this approach does not increase safety and fails to understand the realities of the transportation industry experienced by the transportation workforce. TTD urges HHS to maintain pre-employment drug testing policies as they are currently written. It is not uncommon for individuals in the transportation industry to accept a different job or assignment after the scheduling of their pre-employment drug test. Employees should not be required to report for a test or penalized for failing to do so when they decide not to pursue or have declined the job for which the test is required. There are some types of workers, such as flight attendants or sailors, who may interview with several employers in a short period of time and receive many job offers before accepting one. No safety purpose is served by requiring employees who do not accept a safety-sensitive position to take a drug test, or cause them to suffer the consequences of being deemed a "refusal," comparable to a positive drug test. If individuals under such a mandate do

appear and take such drug tests to avoid these consequences, such testing would be outside of the employment process, serve no safety purpose, and could violate federal or state law. For these reasons, we oppose the provision and urge HHS to remove it from the proposed guidelines.

Opiate Levels and Medical Review Officer (MRO) Investigation

HHS has a duty to ensure that workers who refrain from illegal drug use do not wrongfully test positive and suffer the consequences. We oppose any drug testing parameter that could result in a worker testing positive for a drug that they have not used, through reasonable and legal consumption of food products, testing metrics that have not been adequately studied, or any other reason. Even standards that would result in highly unlikely false positive test results are simply unacceptable given federal drug testing standards apply to millions of workers. The statistically unlikely will absolutely occur given a large enough sample size.

It is incumbent upon the federal drug testing program and MROs to rule out ingestion of food products such as poppy seeds before declaring a positive drug test. The proposed cut off levels of 4,000 ng/mL for morphine and 2,000 ng/mL for codeine are based on "regular consumption" and "regular preparation" of poppy seed food products without a precise definition for those terms, which could complicate these determinations. There are tremendous varieties of poppy seeds used in the production of multiple consumable products, including poppy seed oils, pastes and the use of cooked or raw poppy seeds as an ingredient for many food and beverage recipes. It is not uncommon for an employee to test above the current 2,000 ng/mL opiate cutoffs. In one study, participants ate poppy seed paste during breakfast for three days, and their opiate levels exceeded 2000 ng/mL up to 12 hours post consumption in collected urine samples.[3]

The proposed cut off levels of 4,000 ng/ml for morphine and 2,000 ng/ml for codeine reduces but does not eliminate the number of positives that may be attributable to poppy seed ingestion. Contrary to HHS's statements that "The literature is consistent in the conclusion that regular ingestion of poppy seed-containing foods (bagels, cakes, curries, etc.) rarely results in urine opiate concentrations above the 2,000 ng/mL cutoff specified in the current UrMG," there are numerous studies that say otherwise. In an HHS cited study, ingestion of poppy seed streusel or Danish pastry led to confirmed morphine positive specimens >4,000 ng/mL and codeine positive specimens >2,000 ng/mL.[4] In another study, 10 subjects were given 150g of poppy seeds to eat each day for over 3 weeks. The range of morphine values for the subjects was 2,929 to 13,827 ng/mL morphine.[5]

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[3] Özbunar, Emine & Aydoğdu, Melike & Aslan, Rukiye & Bostanci, Halil ibrahim & Koruyucu, Meryem & Akgür, Serap. (2018). Morphine Concentrations in Human Urine Following Poppy Seed Paste Consumption. Forensic Science International. 295. 10.1016/j.forsciint.2018.11.026

[4] Selavka, C.M, 1991. Poppy seed ingestion as a contributing factor to opiate-positive urinalysis results: The pacific perspective. J. Forensic Sci, 36, 685-696.

[5] "Multiple aspects of hair analysis for opiates: methodology, clinical and workplace populations, codeine and poppy seed ingestion (V.Hill, T. Cairnes, C.C. Change, M. Schaffer, J. Anal. Toxicol., 2005-29 (7):696-703)

Given that a threshold of poppy seed use that would not lead to positive drug tests with certainty is currently unavailable, opiate laboratory results <15,000 ng/mL should not be verified as positive unless clinical evidence of abuse or unauthorized use is found. Currently, if a valid medical explanation is provided by the donor, the MRO verifies the result as negative. If no valid medical explanation is provided by the donor and the opiate levels are below 15,000 ng/mL, the MRO may not verify the result as positive unless clinical evidence of abuse or unauthorized use is found. The current requirements protect individuals who may not neatly fit into HHS' description of a regular consumer of regularly prepared poppy seed food products. Raising the morphine cut-off to 4,000 ng/mL has its benefits only if the donor is protected with the continued requirement that the MRO must establish clinical evidence of abuse or unauthorized use in order to verify the specimen as positive for opiate levels <15,000 ng/mL.

MRO Reporting

TTD opposes requiring the MRO to submit semiannual reports to HHS on specimens that were reported as positive by the lab but subsequently negative by the MRO. Such reporting creates a profile of legitimate workplace medication use that otherwise would not be available. We are concerned that these cases could be potentially identifiable if cases were reported by an employer, workplace, working group, or another potentially small group. This reporting will not "provide a clearer picture of illicit drug use by Federal job applicants and employees" as HHS states in the notice. Rather, it would create a database of legal drug use that could violate workers' privacy of personal health information.

Specimen Retention

TTD supports the proposal included in this notice to require laboratories to retain specimens determined to be substituted for one year. Adequate retention is important to protect workers' rights to due process. One year is a reasonable amount of time to retain specimens that could become subject to litigation holds or other appeal procedures.

As discussed above, TTD opposes the proposals which would remove the opportunity for public comment on changes to the Mandatory Guidelines and the drug testing panel. We also oppose redefining specimens that are currently considered "invalid" as "substituted." Additionally, we oppose changing the rules regarding pre-employment testing so that individuals who fail to appear for a pre-employment drug test are considered to have refused the test. We oppose the modification of the procedures regarding opiate levels that removes the requirements for MROs to find clinical evidence of unauthorized drug use before declaring a positive drug test when opiate laboratory results are under 15,000ng/mL. Finally, we oppose creating a requirement for MROs to report to HHS cases that have been reported as positive by the laboratory but subsequently determined to be negative.

In closing, TTD acknowledges that HHS has made a good faith effort to advance public safety. However, any such changes should not come at the expense of time tested procedures which ensure careful review and analysis of new protocols, or erode the due process and privacy protections afforded covered employees. We urge careful consideration of the views and issues raised herein, and consistent modifications in any final guidance.

We appreciate the opportunity to comment on these guidelines and look forward to working with the Department as it moves to finalize these and future requirements.

Sincerely,

Greg Regan
President