October 26, 2023

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Becerra,

The American Public Transportation Association (APTA) represents the $79 billion public transportation industry that provides mobility for millions of Americans each year, directly employs 430,000 people, and supports millions of private-sector jobs. **We write to strongly urge the U.S. Department of Health and Human Services (HHS) to certify laboratories needed to conduct oral fluid drug testing.**

On June 1, 2023, the U.S. Department of Transportation’s (DOT) final rule amending its transportation industry drug testing program to add oral fluid testing procedures for safety-sensitive transportation employees went into effect. Oral fluid drug testing, as an alternative testing methodology to urine drug testing, will provide public transportation agencies several key benefits, including:

- A less invasive specimen collection option for regulated employers and covered employees, eliminating the need for a secured bathroom;
- A gender-neutral specimen collection process;
- An observed specimen collection that may reduce a donor’s ability to tamper with the specimen, or otherwise thwart the testing process; and
- Greater ability for regulated employers to identify more recent use of a substance, which is particularly important in post-accident and reasonable suspicion testing situations.
Although DOT has authorized oral fluid testing under its drug testing program, it cannot be implemented until HHS certifies at least two laboratories to conduct oral fluid drug testing. The new regulation requires at least one HHS-certified laboratory to conduct initial screening and confirmation testing of the primary oral fluid specimen, and a different HHS-certified laboratory to conduct reconfirmation of the secondary specimen (i.e., split specimen) at the employee’s request in the event of a non-negative result. To date, HHS has not certified any laboratories to conduct oral fluid drug testing.

It is also imperative that at least one oral fluid collection device subject to Food and Drug Administration (FDA) regulations is approved or otherwise cleared by FDA to ensure that the oral fluid testing “system” (collection device and laboratory) is implemented as specified by DOT’s final rule. Under DOT’s final rule, an oral fluid collection device will not be permitted to be used unless HHS has approved a certified laboratory to deploy a particular device.

Safety is a core value for APTA members, including both public transit and passenger rail operators. The HHS certification of laboratories to perform oral fluid drug testing and the FDA clearance of collection devices will allow our agencies to continue to provide the highest level of safety and detection, while reducing illicit drug use in the federal workplace.

Thank you for your prompt attention to this matter. Your swift action will demonstrate that strong interagency coordination between HHS and DOT will continue to allow the public transportation industry to further strengthen its safety goals.

If you or your staff have any questions regarding this issue, please contact me or Ward McCarragher, Vice President, Government Affairs and Advocacy, at wmccarragher@apta.com.

Sincerely,

Paul P. Skoutelas
President and CEO

cc: The Honorable Miriam E. Delphin-Rittmon, Assistant Secretary for Mental Health and Substance Abuse, U.S. Department of Health and Human Services
The Honorable Robert M. Califf M.D., MACC, Commissioner of Food and Drugs, Food and Drug Administration, U.S. Department of Health and Human Services
The Honorable Peter Buttigieg, Secretary, U.S. Department of Transportation
The Honorable Nuria Fernandez, Administrator, Federal Transit Administration, U.S. Department of Transportation
The Honorable Amit Bose, Administrator, Federal Railroad Administration, U.S. Department of Transportation