Congress of the United States
Washington, DC 20515

April 16, 2026

The Honorable Robert F. Kennedy, Jr.
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Modernizing Federal Workplace Drug Testing — Removing the Regulatory Barrier to Oral Fluid and Program Innovation

Dear Secretary Kennedy:

We write to urge the Department of Health and Human Services to take immediate action to remove regulatory barriers that are preventing the timely adoption of oral fluid drug testing and impeding innovation within federally regulated workplace drug testing programs.

As you know, these programs—covering private-sector workers subject to U.S. Department of Transportation and Nuclear Regulatory Commission regulations and federal employees under the HHS regulations for mandatory drug testing—serve a critical public safety mission. These are not clinical diagnostic programs, yet current regulations treat them as such, creating delays that now threaten the relevance and effectiveness of the entire program. Safety-sensitive sectors, including but not limited to commercial aviation, trucking, rail, public transit, and pipelines, rely on efficient, reliable drug testing to maintain the highest standards of public safety. Meaningful modernization, however, remains blocked.

Although oral fluid testing was approved for regulated use in 2023, no U.S. laboratory has been able to achieve certification because of regulatory barriers at the FDA. Regulated employers therefore cannot utilize this reliable, flexible, and directly observed testing method, which allows detection of recent drug use and a more effective response to today's rapidly evolving drug threats. In fact, absent regulatory action, it is possible that U.S. employers will only be able to access federally authorized oral fluid testing by sending specimens to Canada—only a Canadian laboratory has applied for National Laboratory Certification Program (NLCP) oral fluid certification.

The primary obstacle to adoption is the FDA's 510(k) clearance requirement. Under the Employment & Insurance exemption (82 Fed. Reg. 31,976), the FDA explicitly excluded federally regulated workplace drug testing, routing any new test, specimen type, or drug panel update through the FDA 510(k) medical device clearance pathway—a process designed for clinical patient diagnostics that does not account for the forensic and occupational standards that govern workplace testing. The result is a structural misalignment that has delayed access to scientifically validated testing methods for programs covering more than 6.5 million DOT-regulated workers and hundreds of thousands of federal employees.

Removing these regulatory barriers would also provide employers with reliable alternatives to address the ongoing and alarming rise in urine testing subversion—an issue that has generated a niche industry of sophisticated products designed to defeat drug tests. According to an analysis of Quest Diagnostics

data, substituted and invalid drug specimens—two common forms of drug test subversion—increased over 370% and 36%, respectively, from 2022 to 2023 among federally regulated, safety-sensitive employees.[1] Oral fluid, hair, and other directly observed specimen types significantly reduce the opportunity for specimen substitution and have demonstrated higher positivity rates as a result. These alternative testing methods offer the critical safeguards needed to keep impaired workers from operating on our nation's roads and transportation systems and protect public safety.

Importantly, moving these programs out of FDA's clinical device framework would not reduce oversight. The Substance Abuse and Mental Health Services Administration (SAMHSA) through its Division of Workplace Programs and the NLCP already provide rigorous, specialized oversight tailored to forensic workplace testing—including semi-annual laboratory inspections, strict method validation, proficiency testing, and chain of custody requirements. That oversight meets or exceeds what FDA clearance adds for this non-clinical use case. SAMHSA has already removed any reference to FDA clearance requirements for collection and testing devices from their Mandatory Guidelines for Federal Workplace Drug Testing Programs.

Additionally, removing these regulatory hurdles would pave the way for timely adoption of hair testing for regulated transportation employers once HHS completes its mandated rulemaking process. In the Fixing America's Surface Transportation (FAST) Act of 2015 (P.L. 114-94), Congress directed HHS to develop the necessary mandatory guidelines so that hair drug testing may be recognized as a valid alternative to urine tests for commercial motor vehicle drivers.[2] Congress recently reaffirmed this directive by once again instructing HHS to produce hair testing guidelines in the FY2026 Consolidated Appropriations Act.[3] However, over a decade since the original directive, HHS Guidance still has not been finalized, delaying its use for DOT-mandated tests.

While we appreciate that FDA has several of the above matters under review, the pace of progress has not matched the urgency of the need. We respectfully request that HHS take the following actions:

1. **Remove the exclusionary E&I exemption language** that explicitly excludes federally regulated workplace drug testing programs and affirm that laboratory-based workplace drug testing is non-clinical and outside FDA medical device authority.

2. **Recognize SAMHSA and the NLCP** as the governing oversight framework for federally regulated workplace drug testing programs, consistent with how these programs already operate in practice.

3. **Direct SAMHSA's Division of Workplace Programs** to serve as the authoritative body for future updates to drugs, cutoffs, testing technologies, and specimen types, ensuring the federal program can remain current and responsive to evolving public safety threats.

4. **Finalize the hair testing guidelines** as directed by Congress over a decade ago. While the above steps would pave the way for hair testing to be implemented by regulated employers as a drug testing tool, this can only happen if HHS promptly finalizes its long-overdue rule.

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[1] https://newsroom.questdiagnostics.com/2024-05-15-Workforce-Drug-Test-Cheating-Surged-in-2023,-Finds-Quest-Diagnostics-Drug-Testing-Index-Analysis-of-Nearly-10-Million-Drug-Tests

[2] See 49 USC §31306(b)(1)(A).

[3] See Joint Explanatory Statement to accompany P.L. 119-75, the FY2026 Consolidated Appropriations Act.

These are administrative in nature and can be advanced through rulemaking or regulatory guidance without requiring Congressional authorization. HHS has the authority to act now.

We respectfully request that HHS respond with the specific steps it plans to take to take the address these issues, along with an estimated timeline for doing so within 30 days.

Thank you for your prompt review and response.

Sincerely,

Andy Harris, M.D.
Member of Congress

Ben Cline
Member of Congress

Pete Sessions
Member of Congress

Mike Bost
Member of Congress

Mike Collins
Member of Congress

Claudia Tenney
Member of Congress