

DOT Oral Fluid Executive Summary

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The Disclaimer

I am an employee of the United States Department of Transportation (DOT) on detail to the National Drug and Alcohol Screening Association (NDASA) as the Senior Policy Executive Advisor. The views reflected here are expressed in my personal capacity.

My views have not been subjected to review, clearance, or approval by DOT, and they do not necessarily represent the views of DOT.

Webinars, Podcasts, and Presentations – Oh my!

- This will not be a recap of the ODAPC and OraSure Webinars or the Truck Safe podcast.
 - ✓ Those are recorded and available to you.

From HHS to You (via me)

- Ron Flegel informed me last week, for the purpose of conveying information to you at the NDASA conference, that:
 - ✓ "there is significant interest" from labs wanting to obtain certification to conduct oral fluid testing.
 - ✓ "HHS is working with the laboratories and application process to make sure this goes smoothly."
 - ✓ "HHS Certification usually takes around 3 to 6 months from the point an application is received."
 - ✓ "All documents are final for NLCP like the collection, MRO Guidance Manual, etc."

Urban Myths and Legends

- DOT says we can now implement oral fluid testing!

✓ **Not yet!**

- ✓ HHS needs to certify at least two labs (a primary and a secondary lab) before testing can begin.
- ✓ Each lab will be allowed to use **ONLY** the oral fluid collection device(s) they are certified by HHS to use.
- ✓ No oral fluid collectors can be qualified to perform oral fluid testing under Part 40 until devices are identified for each lab and the collectors are trained on those specific devices.
- ✓ Remember, DOT's Part 40 will not allow most devices currently on the market.

Urban Myths and Legends

- There will no longer be urine directly observed collections!

✓ **Wrong!**

- ✓ It will be the employer's option as to when oral fluid or urine testing is to be used and that choice needs to be expressed to the collection site.
- ✓ For the extraordinarily rare circumstance of a directly observed collection being needed for a transgender or nonbinary individual, an oral fluid collection is mandated for the directly observed collection.

Urban Myths and Legends

- Oral fluid collections will be brought in-house by employers and external collectors will no longer be needed!
 - ✓ **That's up to industry!**
 - ✓ Employers have always had the option to do in-house urine collections, but they rarely do.
 - ✓ Anyone conducting oral fluid testing will need to have:
 - Oral fluid collectors trained and qualified under DOT's regulation, "Part 40".
 - A contract with an oral fluid laboratory (and arrangements for paying for a split specimen).
 - A supply of oral fluid collection devices that are NOT EXPIRED.
 - ✓ In the public comments, many employers said they would NOT bring collections in-house
 - ✓ Some noted the costs of training employees to collect and keeping them current on collections.
 - ✓ Some said they did not want the liability of having the Human Resources person who collected the specimen also be the person involved in the disciplinary action or termination of the employee who has a non-negative result.

Let's Get Down to Business

- This will be the first time in “history” two different methodologies for Federal Testing are possible – **AFTER HHS APPROVES 2 LABS** (a primary and a secondary lab).
 - ✓ A change in mindset is needed for employers and service agents.
 - ✓ Now there are choices!
 - What are the choices?
 - Where are the business opportunities?

Business Choices for Laboratories

- Existing and/or future clients are awaiting word from you: Will you offer oral fluid testing?
 - ✓ If so, what device(s) will you use?
 - Will you choose one or more buffered devices and/or a neat device?
 - Be prepared to explain to clients why you have chosen the device(s) selected
 - ✓ Will you charge separately for the devices or include them in the cost of each oral fluid test?
 - ✓ When you apply to the Department of Health and Human Services' National Laboratory Certification Program, will you let your clients know that testing is on your horizon or will you wait until approved?

Business Choices for Employers

- Have you started thinking about your “standing order” (aka instructions) to your collectors?
 - ✓ You will need to instruct your collection sites directly or through a C/TPA as to what type of testing you want used in what kind of situation.
 - ✓ Even if you only want one methodology used, you will want to be clear about it.
- Are you interested in implementing oral fluid testing for your employees?
 - ✓ Why or why not?
 - ✓ Are you working with a C/TPA or do you directly contract with a lab for urine testing?
 - Ask them about the advisability and costs of the various choices.

Business Choices for Employers

- Do you want to use external collectors to perform oral fluid collections, or do you want to train your staff to perform oral fluid collections?
 - ✓ Do you perform urine collections and breath alcohol testing in-house now?
 - If so, you know the upsides and downsides of internal collections and you probably are using staff who have no working relationship with donors and who would not be involved in taking disciplinary actions.
 - ✓ If you do not currently perform in-house collections, here are some considerations for bringing oral fluid collections in-house:
 - Do you have staff who have no working relationship with donors and who will not be involved in disciplinary actions who can perform the oral fluid collections?
 - **If not, and you want to start internal collections consult local counsel about the liability issues!!!**
 - Is it worth your time and money to train your own personnel to collect specimens occasionally?
 - Are you willing to keep oral fluid collection devices, which have expiration dates, on hand at your place of employment?
 - What if an employee is called for a drug test and an alcohol test? – Will you conduct one test in-house and send the employee to an outside location for the other?

Business Choices for Consortiums/ Third Party Administrators

- ***This is a business and marketing opportunity like you have never seen before!***

- ✓ You are welcome!

- ✓ Start NOW, before the post HHS-certification rush, to design “Sample Standing Orders” for your clients!

- Put yourself in the driver’s seat of what testing methodology is the best for each situation and then market this to your clients in the form of standing orders!

- What do you recommend for each test type (i.e., pre-employment, random, reasonable cause/ suspicion, post-accident, return-to-duty and follow-up)?

- What do you recommend for problem collections (e.g., shy bladders, dry mouths, a urine collection that needs to go to a direct observation)?

Business Choices for Consortiums/ Third Party Administrators

- ***This is a business and marketing opportunity like you have never seen before!***
 - ✓ Develop your standing orders in a way that lowers costs and maximizes efficiency – and explain the reasoning to your DOT-regulated clients.
 - ✓ Will your client need an employer policy to describe and/or support their standing order that you drafted?
 - ✓ Once labs are HHS-certified, you can establish contracts and let your collection sites know which labs you will use and what collection devices are needed.

Business Choices for Collector Trainers

- How will you prepare for training future oral fluid collectors?
 - ✓ Do you know which urine collectors want to be trained for oral fluid collections?
 - ✓ **It's too early to do much else beyond Train-the-Trainer courses.**
 - ✓ It's a bad idea to train collectors before the labs are approved to use specific devices because **no collectors can be QUALIFIED under Part 40 without performing mock collections on the devices they will use.**

Business Choices for Collection Sites & Independent Professional Collectors

- Do you want to offer oral fluid testing?
 - ✓ If not, you will need:
 - To be clear about an employer's "standing order" and be prepared to follow that employer's directions;
 - An action plan for how you will transfer to an oral fluid collector any transgender or nonbinary individual who needs a directly observed collection.

Business Choices for Collection Sites & Independent Professional Collectors

- If you do want to offer oral fluid testing:
 - ✓ You will need:
 - To be clear about an employer's "standing order" and be prepared to follow that employer's directions;
 - To have access to and proficiency training under Part 40 for the specific devices the HHS-certified lab requires
 - ✓ Wait until the labs are approved and the devices are known before conducting collector training because **no collectors can be QUALIFIED under Part 40 without performing mock collections on the devices they will use.**