

What Service Providers Can Do Now to Prevent Collector Disputes Later



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Problems in Collections



- Collector qualifications and CCF
- Specimen types and alternative specimens
- Refusals to test
- Observed collections
 - When to perform
 - How to perform (who can perform)?
- Shy bladder procedures

Applicable laws



Federal Law

- U.S. Department Health and Human Services (HHS) mandatory guidelines for federal workplace Drug Testing Programs
- U.S. Department of Transportation (DOT) Drug Testing Regulations (49 CFR Part 40)
 - Drug testing regulations for safety-sensitive employees in transportation industry
- Federal law includes detailed procedures and defined roles and responsibilities for each entity involved in collection process

Federal Law Update



DOT

- Revised DOT Drug testing regulations Part 40 effective January 1, 2018
- Revised Urine Specimen collection guidelines — January 2018
- Monitoring collection sites (guidance and best practices) — May 2016

HHS

- Revised SAMHSA Mandatory Guidelines effective October 1, 2017
- Revised Collection Handbook — October 1, 2017
- Revised MRO Manual

Federal Law Update – DOT



Nov. 13, 2017: U.S. DOT published final rule to amend drug testing regulations (49 C.F.R. Part 40)

- Rule effective January 1, 2018
 - Revisions to harmonize DOT regulations with revised HHS mandatory guidelines for federal drug testing programs
- Summary of changes related to collections
 - Revised CCF (August 2017 CCF)
 - Shy bladder process
 - New section to clarify only urine specimens by HHS certified laboratories authorized for DOT testing (hair, oral fluid, POCT not permitted) (40.210)
 - Collectors (and other service agents) must subscribe to ODAPC list-serv
 - Addition of 3 fatal flaws related to collection
 - Prohibition from using DOT or DOT agency name, logos, other official branding
 - Alcohol testing device web links

Federal Law Update – HHS



Jan. 23, 2017: U.S. HHS published final rule to amend mandatory guidelines

- Rule effective October 1, 2017
- Summary of changes related to collections
 - Revised CCF
 - Observed collection procedures: gender of observer now based on gender identity of donor
 - Refusals to test: bringing adulterant or substitution product to collection site now considered refusal to test, before required observed collection
 - Insufficient specimens/allowing alternative specimens (in anticipation of oral fluid specimens)
 - Shy bladder procedures
 - Addition of fatal flaws

Applicable State Laws



Numerous State laws govern or impact workplace drug testing programs

❖ Mandatory Drug Testing laws

- Must comply with statutory/regulatory requirements
- Some are industry specific (i.e., public employees, Miners, etc.)

❖ Voluntary Drug Testing laws

- Compliance not mandatory but employer that complies with requirements entitled to certain legal benefits (E.g., Arizona, Mississippi, West Virginia)

❖ Mandatory Laboratory laws

- Laws apply to laboratories performing workplace drug testing

❖ Voluntary Workers' Compensation Premium Discount Laws

- Voluntary but compliance entitles to discount on workers' compensation insurance; often detailed requirements

❖ Workers' Compensation and/or Unemployment Benefits Reduction or Denial

State Laws



State laws are complex, inconsistent, and constantly changing

- Collection requirements vary widely
 - Some laws have detailed collection requirements and procedures, while others do not
 - Some states adopt collection procedures of DOT/HHS
- Legal obligations will vary depending on the type of testing, even within the state
 - *E.g.*, Kansas has mandatory laboratory testing law and voluntary workers' comp premium discount; one addresses collection while the other does not
 - Mandatory laboratory law (KAR 28-33-12): no mention of collection
 - Voluntary worker's comp law: must be collected by or under supervision of a licensed health care provider for test results to be admissible as evidence of impairment; split specimen required (44-501(b)(3))
- Participants must be aware of these different schemes

States That Require DOT Collection Procedures



Some states require collection procedures in accordance with DOT procedures

- **Arkansas**—voluntary workers' comp
 - Requires collections in accordance with DOT
- **Montana**—mandatory safety-sensitive
 - Requires collections in accordance with DOT

State Law Examples—Hawaii



Mandatory drug testing law

- Contains blood and urine specimen collection requirements
- Pre-testing notification requirements
- CCF requirements/limitations
- POCT limited: if positive, must be directed to Hawaii licensed laboratory within 4 hours
- Observed collections limited
- References Shy Bladder
- If immediate collection necessary and no third party collection site available, public restroom can be used (11-113-6(9))
 - Same gender collection site person shall accompany individual to restroom but remain outside the stall

State Law Examples – Hawaii



Urine specimen collections

- Specimen volume must be at least 30 mL, if less must discard (HAR 11-113-6(a)(10))
- Collection site attendant must measure temperature of specimen within 4 minutes of receiving sample (HAR 11-113-6(12))
 - Must allow donor option to have oral temperature taken (HAR 11-113(6)(15))

Blood specimen collections

- Can only be drawn by a physician, registered nurse, or person with a clinical laboratory personnel license or phlebotomist (HAR 11-113-7(1))
- Blood specimens must be labeled with name of person drawing blood and type or amount of preservative or anticoagulant used (11-113-7(4))

State Law Examples – Iowa



Mandatory Drug testing law

- Split specimens required for current employees; urine volume limits (§ 730.5(7)(b))
- Pre-testing notification requirements (§ 730.5(7)(c)(2))
- Direct observation collections limited
- 2017: law amended to allow hair specimens for pre-employment testing only (still prohibited for employees)
 - No guidance on collection procedures
 - Limits testing to 1 ½ inches of hair closest to scalp

State Law Examples – Iowa



Mandatory drug testing law (continued)

- No employer-mandated blood alcohol testing (730.5(7)(f)(2))
 - Exception: employer may rely on blood test results only if blood collected post-accident by treating healthcare professional without request or suggestion by the employer that test be conducted (730.5(7)(1); IAC 641-12.2)
- Breath alcohol testing must be performed in accordance with DOT regulations (730.5(7)(f)(2))
 - 2017: Law amended to DOT regulations in effect July 1, 2017

State Law Examples – Maine



Mandatory drug testing statute

- Specimen must be collected at a medical facility under supervision of a licensed physician or nurse (26 MRS § 683(2)(C)(I))
 - Medical facility includes a first aid station located at the work site
- Observed collections prohibited (683(2)(C)(3))
- At request of donor at collection, portion of the sample must be segregated for that person's own testing (683(5)(A))
- At time of collection, employee may request blood specimen for marijuana and alcohol testing if those substances are tested for under employer's written policy (683(5)(B))
 - Blood must be collected by a licensed physician, registered physician's assistant, registered nurse, or person certified by Maine DHHS
 - If requested, no other sample may be tested for alcohol or marijuana metabolites

State Law Examples—Maine



Maine also has mandatory drug testing laboratory requirements

- Contains collection procedures for each specimen type
 - Urine collections
 - If employer's policy calls for specimen assessment, collector may, in presence of donor, measure the temperature of the specimen within 3 minutes of voiding, the pH of the specimen, and evaluate the color and odor (CMR 10-144-265(B)(4))
 - Blood collections
 - Must be taken by a licensed physician, registered physician's assistant, registered nurse, or person certified by Maine Department of Human Services to draw blood (CMR 10-144-265(B)(5))
 - Oral fluid, hair, and sweat
 - Must be collected in accordance with 2004 proposed federal regulations (265(B)(6)–(8); CMR 10-144-265(B)(6)–(8))

State Law Examples—Oklahoma



Mandatory drug testing statute

- Detailed regulations for collections of various specimen types (urine, hair, saliva, blood, breath)
- Collector qualification and training requirements
 - Collectors must be certified by State Board of Health (§ 559)
 - Documented training record or medical professional/technician who has acknowledged in writing that has instructions (OAC 310:368-1-10); must provide employer representatives with standard written instructions (OAC 310:638-1-10)
- Limitations on direct observation urine
- Shy bladder procedures

State Law Examples – North Carolina



Mandatory drug testing

- No detailed collection requirements
 - Collection must be under reasonable and sanitary conditions
 - May be collected on site or at approved lab (§ 95-232(b))
- If employer contracts with third party for collection or testing, must ensure contractor's procedures comply with statute's collection requirements
- POCT limitations (§ 95-232(c)(1))
 - Permitted for testing of applicants only, prohibited for employees
 - POCT must be FDA approved and using HHS cut-offs (20.0101(6))

State Law Examples: Vermont



Mandatory drug testing statute

- Only urine specimens permitted
- Contains collector certification requirements and specifies who may not be collector (511(8))
- Permits alternative specimen at donor's request
 - Must provide donor with opportunity at donor's expense to have blood sample drawn at time of urine sample to be later tested for drugs (514(6)(B))
- Specimen preservation responsibility of collector
 - Provides that the collector must ensure that a portion of any positive specimen is preserved in a condition to permit accurate retesting for not less than 90 days after donor receives result (514(10))

State Law Examples: Illinois



Mandatory Post-Accident Workers' Comp testing

- Requires 7 part CCF with detailed requirements
- Detailed regulations for collecting blood, urine, and breath
 - Urine Specimen Collections
 - Must be collected by collector meeting training requirements of 49 C.F.R. 40.33 (2012), licensed physician, advanced practice nurse, registered nurse, or licensed practical nurse (50 Ill. Adm. Code 9140.20(a))
 - Specifies who may not serve as a collector: Immediate supervisor of employee being tested unless no other collector available; or person employed by lab who could link employee with a urine specimen, testing result, or laboratory report (50 IAC 9140.30(a))
 - Provides additional detailed guidance on the collection process (*i.e.*, observed collections)
 - Blood Specimen Collections
 - Must be collected by a licensed physician, advanced practice nurse, registered nurse, licensed practical nurse, phlebotomist, or certified paramedic (50 Ill. Adm. Code 9140.20(a))
 - Must be collected using aseptic venipuncture technique (9140.20(b)(3))
 - Venipuncture site must be cleansed with antiseptic substance that does not contain ethanol prior to collection (9140.20(b)(4))
 - Must collect sufficient amount to permit split testing (9140.20(b)(5))

State Law Examples: Tennessee



Voluntary Workers' Compensation

- Rules revised, effective May 6, 2018
- Revised to permit POCT for pre-employment testing only (0800-02-12-.05(1)(a))
 - Device must use U.S. DOT and HHS testing standards and be approved by the Tennessee Bureau of Workers' Compensation
 - Must use HHS cut-off levels for Initial Screening
 - All positive tests must be confirmed by a certified laboratory
- New provisions regarding refusals (0800-02-12-.06)
 - If an employee is unable to provide a urine specimen, must follow HHS mandatory guidelines on oral fluid and alternative specimen collection
 - If an employee with a presumed positive for failure to submit a specimen wishes to contest the finding, DOT Shy Bladder and Shy Breath policies shall be followed at employer's expense

Pre-testing/collection notification



State Law Examples

- **Oklahoma**—mandatory
 - Collection documentation procedure shall include opportunity for donor to provide notification of any information donor considers relevant to test (§ 559)
- **Hawaii**—mandatory
 - Individual being tested must be provided a list of the specific substances to be tested for and a statement that over-the-counter or prescribed drugs may result in positive test results; no one may test for drug not listed (§ 329B-5(a) & 11-113-5(a))
- **North Carolina**—mandatory
 - When provide specimen, must provide written notice of rights and responsibilities under Act (13 NCAC 20.0401)
- **Iowa**—mandatory
 - Donor must be given opportunity to provide information on current medication or other relevant medical condition; such information must be documented; employer must provide donor with list of drugs to be tested

CCF Requirements



Federal Law

- DOT: Revised CCF (August 2017 CCF)
 - Collectors may use old CCF until June 30, 2018
 - Use of previous CCF until June 30, 2018: no MFR required
 - If after June 30, 2018: must complete MFR (40.205(b)(2))
- Collectors must subscribe to ODAPC list-serv

CCF Requirements



State law CCF requirements

- **Vermont**—mandatory
 - CCF must assure anonymity of individual (no name on CCF) (514(5))
- **Hawaii**—mandatory
 - CCF “coded” identity of individual being tested (no name on CCF but may contain social/employee ID) (HAR 11-113-27)
- **Florida**—voluntary workers’ comp premium discount
 - Must be collected on a Florida form
- **Illinois**—mandatory post-accident testing
 - 7 part CCF

Collector Qualifications



State law collectors requirements/limits

- **Maine**—mandatory
 - Collector must be health care professional
- **Oklahoma**—mandatory
 - Collector must be qualified by the state (559)
 - Training records
- **Vermont**—mandatory
 - Collector must be “certified” as HHS-approved collector
 - Must be recertified every 3 years
 - Collector cannot be employee of employer for drug testing based on probable cause (only permitted for applicant testing) (511(8), 514(12))

Urine Specimen Volume Requirements



- **Hawaii**—mandatory
 - Specimen volume must be at least 30 mL (11-113-6(a)(10))
- **Oklahoma**—mandatory
 - Must collect 45 mL if split, 30 mL if single (310:638-1-8(10))
- **Maryland**—mandatory
 - Not specified: Must collect quantity sufficient to perform initial screening test, confirmation test, and an independent test (10.10.10.07(B))
- **Iowa**—mandatory
 - For current employees, bottle A must contain at least 30 mL and Bottle B must contain at least 15 mL (730.5(7)(b))
- **Illinois**—mandatory post-accident testing
 - Must collect a specimen of at least 45 mL (9140.30(f)(9))

Alternative Specimens – Federal law



DOT

- New provision to emphasize only urine specimens tested by HHS-certified laboratories permitted for DOT drug testing
 - When a clinical evaluation performed under direction of MRO, MRO may choose to use another testing methodology to clarify that a donor is not using drugs but not to show a positive test result (40.195(a)(3))

HHS

- Revised mandatory guidelines to anticipate oral fluid specimens in shy bladder situations

Alternative Specimens



DOT agency regulations may include circumstances in which testing a specimen other than urine is permitted

- FRA Post-accident testing (49 C.F.R. part 219)
- USCG Post-accident (46 C.F.R. part 4)

Alternative Specimens – State Law



Some states permit alternative specimens (blood) at donor's request at time of collection

- **Maine** – mandatory
 - Employees may request to submit blood specimen for testing for alcohol or marijuana (if substances tested under employer's written policy)
 - If requested, may not test other specimens for marijuana/alcohol
- **Vermont** – mandatory
 - Donor may request blood specimen for testing
- **Nebraska** – mandatory
 - Employee may request blood specimen to confirm positive breath alcohol test
 - Collector must be qualified and licensed; regulations on blood collections for alcohol (177 NAC 1.005)

Hair Collections



- **Maine**—mandatory
 - Hair must be collected pursuant to 2004 proposed federal regulations
- **Iowa**—mandatory
 - In 2017, statute revised to permit hair specimens for pre-employment testing only (still prohibited for employees)
 - No guidance on collection
- **Oklahoma**—mandatory
 - Detailed collection requirements for hair
 - Must be cut as close to scalp as possible
 - Collector must determine it contains approximately ½ inches of hair when fanned out on ruler (40 mg) (310:638-1-8.1(f)(4))
 - Pubic hair collections prohibited
 - Additional hair samples may be collected to reconfirm initial report (OAC 310:638-1-7.1(f))

Oral Fluid Specimen Collections



State Laws

- **Maine**—mandatory
 - Oral fluid must be collected pursuant to 2004 proposed federal regulations
- **Oklahoma**—Mandatory
 - Must be collected in FDA approved device and according to the instructions provided by the manufacturer of the saliva collection device (OAC 310:638-1-8.2)

POCT



Federal law

- POCT prohibited: urine specimens must be tested by HHS certified laboratory
 - DOT new provision clarifying only urine specimens tested by HHS-certified laboratories are authorized

State law

- Some states prohibit POCT
 - *E.g.*, Vermont—mandatory; Montana—mandatory safety-sensitive employees
- Some states have detailed POCT requirements

POCT



State law POCT collection requirements

- **Maryland**—mandatory
 - Collector requirements, HHS cut-offs, registration required; trained operators and training records (10.10.10.10)
 - Voluntary disclosure by applicant permitted
- **Hawaii**—mandatory
 - For positive POCT specimens, donors must report to Hawaii licensed lab within 4 hours; if fails to report to lab, employer may take adverse action but only if donor provided with written notice
 - Collector must be trained by manufacturer
- **North Carolina**—mandatory
 - Permitted for testing of applicants only, prohibited for employees (§ 95-232(c)(1))
 - POCT device must be FDA approved and using HHS cut-offs (20.0101(6))

Observed Urine Specimen Collections



Why perform observed urine collections?

- **For federally regulated employers:** circumstances mandated by law
 - *E.g.*, temperature out of range, return-to-duty, follow-up testing
- **For non-regulated testing:** thriving market for adulterants, prosthetics, and tips to defeat urine drug testing
 - Even if position not safety-sensitive, employee attempts to interfere with a testing program undermine purpose of policy and employer's legitimate interest in promoting a drug-free workplace

How is Observed Collection Performed?



Federal Law

- **DOT**: Be sensitive to the needs of the donor and the observer regarding gender issues.
 - Provides a specific procedure for an observed collection
 - Observer asks donor to raise upper garment above waist and to lower pants/skirt and underpants, and turn around to show that no prosthetic device exists; must watch urine go from donor's body into collection container
- **HHS**: Under new mandatory guidelines, now same-sex observer as determined by donor (and donor's "gender identity")—which may be the same as or different from donor's sex assigned at birth
 - Because of challenges with gender determinations (transgender employees), HHS added definition of "gender identity:" which means an individual's internal sense of being male or female, which may be different from an individual's sex assigned at birth"
 - At beginning of collection, collector requests donor document their gender on CCF and initial annotation; observer of same gender is provided and collector records name and gender of observer on CCF
 - Procedure same as DOT but does not require raising or lowering of clothing or turning around; observer must watch urine go from donor's body into collection container

Observed Urine Specimen Collections



State laws

- A few states prohibit observed collections under any circumstances, while several others limit observed collections
- Additionally, several states adopt DOT or HHS procedures for observed collections
- However, the vast majority of state laws do not provide any statutory or regulatory guidance to employers when or how to conduct observed urine specimen collections
 - This requires critical policy determinations by employers

Observed Urine Collections



Mandatory state laws that prohibit observed urine collections

- Connecticut
- Maine
- Rhode Island

Local laws may also prohibit observed urine collections

- *E.g.*, Boulder, Colorado

Observed Urine Collections



State laws that limit observed collections

- **Hawaii**—mandatory
 - Permitted if reason to believe original specimen was contaminated or if specimen temperature is out of range (HAR 11-113-6(15), (16))
 - Determination made by TPA or DER but must obtain approval of employer
 - If temperature out of range, donor may offer to have temperature taken
 - Must provide same gender observer, and both original and directly observed specimens must sent to lab
- **Iowa**—mandatory
 - Permitted only for reasonable suspicion of alteration or substitution of sample; must use same gender observer
- **Oklahoma**—mandatory
 - Permitted only for 2nd collection after collection of initial specimen; Determination made by collection site

Observed Urine Collections



States that adopt federal standards for observed collections

- **Georgia**—public employees
 - Adopts HHS observed collection procedures
- **Indiana**—Mining industry
 - Adopts HHS observed collection procedures
- **Arkansas**—voluntary workers' comp
 - Adopts DOT observed collection procedures

Observed Urine Collections: Privacy Issues and Claims



Federal Law

- State action- alleging violation of constitutional rights and unreasonable search/seizure
- DOT mandated direct observation collections for all return-to-duty and follow-up testing upheld by Court
 - ***BNSF Railway v. US Dep't of Transp.*, 566 F.3d 200 (DC Cir. 2009)**
 - Court found not arbitrary or capricious and did not violate the Fourth Amendment constitutional prohibition on unreasonable searches and seizures
- Donors often do not understand roles of various entities and assume one participant is involved in all parts of the process; often bring claims against laboratory and/or MRO and/or TPA for actions of collector
 - ***Pasternack v. Lab. Corp. of Am. Holdings*, 59 N.E.3d 485 (N.Y. 2016)**
 - On certified question regarding refusal to test, New York Court of Appeals held laboratory had no duty to comply with DOT regulations that do not implicate scientific integrity of testing process

Observed Urine Collections: Privacy Issues and Claims



For non-regulated private employers:

- No state action; claims generally brought under state constitution or common law right to privacy; not all states have addressed issue
 - *Cook v. Warrior Energy Servs. Corp.*, 2017 U.S. Dist. LEXIS 55310 (W.D. La. Apr. 11, 2017) and *Ron Bros. v. Warrior Energy Servs. Corp.*, 2017 U.S. Dist. LEXIS 55312 (W.D. La. Apr. 11, 2017)
 - Requiring employees to submit to directly observed reasonable suspicion testing and falsely reporting to third parties that employees were tested because of reasonable suspicion may give rise to claims for invasion of privacy and defamation
 - Court denied employer's motion to dismiss

Immediate Re-collection Procedures and “Shy Bladder”



- **DOT Re-collection Procedure — (Jan. 1, 2018)**
 - Collector now required to discard questionable or temperature out of range initial collection if sufficient specimen cannot be collected by observed collection within three hours of first collection
 - MRO would then evaluate as “shy bladder” (40.193(b)(4))

Shy Bladder Procedures



Few state laws address shy bladder procedures, those that do are not consistent

- **Hawaii**—mandatory
 - If insufficient specimen (less than 30 mL of urine), individual may be allowed to drink a reasonable amount of water; time limit not specified
- **Oklahoma**—mandatory
 - If insufficient specimen, collector must instruct donor to drink not more than 24 ounces of fluids and after a period of up to 2 hours, again attempt to collect a specimen
- **Kansas**—workers' comp
 - *Byers v. Acme Foundry*, 2017 Kan. App. LEXIS 12 (KS. Ct. App. Jan. 27, 2017): insufficient urine specimen, w/out evidence of intent to thwart test, is not refusal to submit to a test for purposes of Workers' Compensation Act

Drug Test Cheating Laws



State laws making adulteration/substitution a crime

- Some state drug testing statutes criminalize attempts to adulterate or substitute a specimen
 - *E.g.*, Nebraska—mandatory law: attempting to adulterate or substitute a urine specimen is a class I misdemeanor (48-1908, 48-1909)
- At least 20 states have anti-drug test cheating laws
 - Laws criminalize attempts to interfere with a drug and/or alcohol test
 - Laws vary widely
 - May have severe penalties
 - *E.g.*, South Carolina—a first offense is considered a misdemeanor subject to a fine of up to \$5,000 , up to 3 years in prison, or both and a second or subsequent offense is considered a felony subject to a fine of up to \$10,000, up to 5 years in prison, or both

Drug Test Cheating Laws



State law examples making adulteration/ substitution a crime

- Some state laws only make it illegal to sell synthetic urine
 - E.g., Indiana (2017)
- Some states criminalize the use of drug-free urine (not adulterants)
 - E.g., Pennsylvania and Virginia
- Some state laws are comprehensive (E.g., Arkansas, South Carolina, North Carolina) and generally prohibit:
 - Selling, giving away, distributing, or marketing urine intended to defraud a drug test
 - Attempting to defeat a drug test by spiking or substituting a specimen
 - Adulterating a specimen
 - Possessing or selling adulterants

QUESTIONS?



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