U.S. Department
of Transportation
Federal Transit Administration
Office of Safety and Security

FTA Drug And Alcohol Regulation *Updates*

Summer 2003 **Issue 25**

Introduction....

The Federal Transit Administration (FTA) published its revised rule on prohibited drug use and the prevention of alcohol misuse (49 CFR Part 655) on August 1, 2001. The FTA published the revised *Implementation Guidelines for Drug and Alcohol Regulations in Mass Transit* to provide a comprehensive overview of the regulations.

Since the *Guidelines* were published, there have been numerous amendments, interpretations, and clarifications to the Drug and Alcohol testing procedures and program requirements.

This publication is being provided to update the *Guidelines* and inform your transit system of these changes. This Update is the twenty-fifth in a series.

Inside....

HIPAA and DOT Rules Don't Conflict

The Department of Health and Human Services (HHS) promulgated a rule under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) that established national standards for safeguards to protect the integrity, confidentiality, and availability of electronic health information. The rule covers the risk of improper access to stored information and the risk of interception during electronic transmission of information.

The HHS HIPAA rule requires the consent or authorization from an individual any time information is released regarding a person's "preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care or the past, present, or future physical or mental health or condition of an individual." Information obtained as part of a Department of Transportation (DOT) drug and alcohol testing program is not considered "health information" covered by HIPAA rules and therefore, does not require employers and service agents in the DOT drug and alcohol testing program to obtain written employee authorization to disclose drug and alcohol testing information required by DOT and FTA rules (49 CFR Parts 40 and 655, respectively). The DOT/FTA testing program only considers the employee's compliance with safety regulations and does not address any employee health considerations.

In addition, Part 164.512 of the HHS rule further explains that employee authorization is not necessary where Federal law requires the use or disclosure of otherwise protected health information. Parts 40 and 655 clearly stipulate the specific circumstances that require employee authorization or consent. Required disclosure or use of other information cited by the rules does not necessitate employee authorization or consent.

Consequently, employers do not need employee authorizations to conduct DOT tests. Employers need to notify applicants of the need for a pre-employment test and employees need to be provided with a policy statement that indicates participation in the testing program is a condition of employment, but no employee authorization is required.

Collectors do not need authorizations to perform DOT urine collections, to distribute Custody and Control Forms, or to send specimens to laboratories. Screen Test Technicians (STT) and Breath Alcohol Technicians (BAT) do not need authorizations to perform DOT alcohol tests or to report test results to employers. Laboratories do not need employee authorization to perform DOT drug and validity tests, or to report results to designated Medical Review Officers (MROs).

Likewise, MROs do not need employee authorization to verify drug test results, to discuss alternative medical explanations with prescribing physicians and issuing pharmacists, to report results to employers, to confer with Substance Abuse Professionals (SAPs) and evaluating physicians, or to report other medical information. Evaluating physicians are also allowed to report evaluation information and results to MROs or to employers, as appropriate without employee consent.

SAPs do not need employee authorization to conduct SAP evaluations, to confer with employers, to confer with MROs, to confer with appropriate education and treatment providers, or to provide SAP reports to employers. Consortia/Third Party Administrators are also allowed to bill employers for service agent functions they perform or contract out without employee consent.

Not only does the HHS rule (45CFR Part 164.512) enable employers and service agents in the DOT program to disclose information without the employee's authorization, but additionally, 49 CFR Part 40.355 clearly prohibits any service agent to require individuals to sign consents, releases, waivers, indemnifications, or any other form that is not part of the DOT procedures as defined in Part 40. In conclusion, HHS and DOT both agree that there is no conflict between the HIPAA and DOT rules.

REGULATORY UPDATE

Where To Find?.....

49 CFR Part 655, Prevention of Alcohol Misuse and Prohibited Drug Use in Transit Operations

August 9, 2001
Federal Register Vol. 66
Pages 41996 - 42036

Notice of Interpretation:
April 22, 2002
Federal Register Vol. 67,
Pages 19615-19616
Primary Topic: FTA/USCG regulation applicability to ferry boats.

The information presented on this page should be used to update Chapter 7 of the revised *Implementation Guidelines*.

New Validity Test Standard Announced

After a long and controversial scientific debate, the Department of Health and Human Services (HHS) withdrew its proposed specimen validity testing (SVT) guidelines. In the absence of this guidance and in light of new scientific information, the Department of Transportation (DOT) published an interim final rule (IFR) to establish new dilute and substitute specimen criteria to be used for DOT mandated drug testing. The interim final rule that amended 49 CFR Part 40 was published in the Federal Register (Vol. 68, No. 102, pp 31624-31627) on May 28, 2003.

The need for the change became evident at a recent conference where technical experts disagreed on the minimum creatinine standard that should be used to determine if a specimen is substitute. Previously, the standard used in the DOT drug testing procedures (49 CFR Part 40.93(b)) was a creatinine concentration of less than or equal to 5 mg/dL *and* a specific gravity of less than or equal to 1.001 or greater than or equal to 1.020. This standard was based on studies by the HHS and constituted the best scientific information available at the time the DOT rule was published on August 1, 2001. Since that time, additional information has become available that puts this standard into question including a small number of cases in which individuals may have legitimate medical or physiological explanations for producing specimens with lower levels of creatinine.

This criterion is important because it is the measure used to determine if an employee's specimen is substitute, and therefore, whether it constitutes a test refusal with resulting consequences. The intent was to establish the standard at a level that would eliminate the possibility that an individual could naturally produce such a specimen and thus, would provide evidence of substitution. Recent evidence indicates, however, there is a relatively small number of individuals who are capable of producing creatinine concentrations below the previous standard.

Experts agree that the standard should be lowered. The level should be low enough to ensure that individuals are not unfairly charged with substitution, however, the level must be high enough to identify individuals that substitute specimens to evade detection of drug use. While awaiting HHS guidance, the DOT decided to publish the interim final rule setting forth the following four basic provisions.

1. Laboratories are directed to report to MROs the creatinine and specific gravity quantifications for all DOT specimens that meet the regulatory substitution criteria (§40.93).
2. Laboratories must provide quantitative values only when the concentration is above their minimum detection limit. Any reading below the minimum limit must be reported as "creatinine not detected."
3. If a creatinine level of a specimen is less than 2mg/dL or "creatinine not detected," the MRO must report the specimen as "substituted." If a creatinine level of a specimen is greater than or equal to 2mg/dL, but less than 20mg/dL, the MRO must report the specimen as "dilute" and negative or positive.
4. If a specimen has a creatinine level greater than or equal to 2mg/dL but less than or equal to 5 mg/dL, the MRO must also direct the employer to require the employee to undergo an unannounced immediate recollection under direct observation and the employer must make sure the recollection takes place.

The rule did not change regarding specimens with creatinine levels above 5 mg/dL, but less than 20 mg/dL. In these cases, the employer determines whether to require a retest as a matter of policy. If negative dilute retests are required under this threshold, they may not be performed under direct observation (§40.197).

Laboratories are not currently required to conduct validity testing as part of the DOT testing program, but those that do, must follow the current standard. As with the previous rule, any individual that provides a specimen below the current standard (i.e., less than 2 mg/dL) has the ability to challenge the substitute determination by demonstrating that there is a legitimate medical explanation for the result following the procedures outlined in §40.145.

The DOT is requesting public comments on the IFR by August 26, 2003. Comments should refer to Docket Number OST-2003-15245 and should be sent to the Docket Management System, USDOT, Room PL-401, 400 Seventh Street, S.W., Washington, D.C. 20590-0001 or electronically to http://dms.dot.gov/.

Clarifications & Corrections

Lift Accidents May Require Test

The accident definition and post-accident testing requirement defined in FTA's drug and alcohol testing regulation (49 CFR Part 655) has not changed, but an important clarification of the rule was provided by Mark Snider of the FTA Office of Safety and Security at a recent Community Transportation Association of America conference.

The rule (§655.4) defines an accident as an occurrence associated with the operation of a vehicle in which:

- An individual dies; or
- An individual suffers bodily injury and immediately receives medical treatment away from the scene of the accident; or
- In the case of an occurrence in which the mass transit vehicle (including non-FTA funded vehicles) involved is a bus, electric bus, van, or automobile, one or more vehicles incurs disabling damage as a result of the occurrence and requires removal away from the scene by a tow truck or other means; or
- In the case of an occurrence in which the mass transit vehicle is a rail car, trolley car, trolley bus, or vessel, the mass transit vehicle is removed from operation.

Previously, FTA provided guidance that an "occurrence associated with the operation of a vehicle" meant that the accident had to be directly related to the manner in which the driver applied the brake, accelerated, or turned the steering wheel. Given this focus on the actual movement of the vehicle, incidents involving the operation of lifts were determined to be outside the accident definition and therefore would not require FTA post-accident drug and alcohol tests.

Upon further consideration, FTA has determined that since lifts constitute equipment used in revenue service and their operation is essential to the operation of the vehicle and protection of public safety, their operation should be included in the accident definition. Therefore, FTA clarified its' position expanding its interpretation of "operation of a vehicle" to include operation of its lift. Thus fatalities associated with the operation of a lift will require the conduct of FTA drug and alcohol post-accident tests for the driver and any other covered employee that could have contributed to the accident. Non-fatal accidents associated with the operation of the lift that result in bodily injury requiring immediate transportation to a medical facility will also require the conduct of FTA drug and alcohol post-accident tests unless the employee can be completely discounted as a contributing factor consistent with §655.44.

Rx/OTC Toolkit Available

The FTA *Prescription and Over-The-Counter Medications Toolkit* was developed in response to a growing concern about the use of prescription (Rx) and over-the-counter (OTC) medications that can affect the performance of safety-sensitive duties. On May 22, 2000, FTA issued a "Dear Colleague" letter encouraging grantees to review current policies with regard to operators' use of Rx/OTC medications which could result in risks to public safety and institute educational programs that address the potential dangers of taking certain types of medications. To assist grantees in their effort, FTA created a toolkit of sample policies, procedures, training materials, and post-accident documentation procedures that are currently in use at various transit agencies across the country. The toolkit also contains two appendices. The first contains lists of prohibited Rx/OTC medications used by various Federal and private agencies and the latter includes a list of references and resources.

The toolkit was posted on the FTA website in May. To download the document, go to http://transit-safety.volpe.dot.gov/publications. Print copies will be mailed to grantees in August. If you would like to order a print copy contact Ms. Alison Thompson at thompsona@volpe.dot.gov or fax your request to (617) 494-2684.

Where To Find?.....

49 CFR Part 40, Procedures for Transportation Workplace Drug Testing Programs

Revised:
December 19, 2000
Federal Register Vol. 65,
Pages 79462-79579.
Primary Topic: Procedures for Transportation Workplace Drug and Alcohol Testing Program Revised Final Rule
(49 CFR Part 40)

Technical Amendments:
August 1, 2001
Federal Register Vol. 66
Pages 41943-41955
Primary Topic: Clarifications and Collections to Part 40; Common Preamble to Modal Rules

Notice of Proposed Rulemaking
September 30, 2002
Federal Register Vol. 67
Pages 61306-61313
Primary Topic: MIS Reporting

Interim Final Rule
May 28, 2003
Federal Register Vol. 68
Pages 31624-31627
Primary Topic: Substitute and Dilute Specimens

The information presented on this page should be used to update Chapters 5 and 6 of the revised *Implementation Guidelines*.

FOR YOUR INFORMATION

Where to Find? .....

DHHS Labs

The current list of DHHS certified labs is published the first week of each month and is printed in the Federal Register under the Substance Abuse and Mental Health Services Administration (SAMHSA) heading. Only those labs certified can be used for FTA drug testing. The list should be checked monthly as new labs are being added and others are being removed.

Website location: http://www.workplace.samhsa.gov/ResourceCenter/lablist.htm

To verify the certification status of a laboratory, DHHS has established a telephone HELPLINE (800) 843-4971.

The information presented on this page should be used to update Chapter 12 of the revised *Implementation Guidelines*.

Effective Oversight Need Not Be Costly

All FTA grantees and subrecipients are responsible for the full compliance of their system with the FTA drug and alcohol testing regulations including their contractors that perform safety-sensitive job functions. The only safety-sensitive contractors that are exempt from the rules are maintenance contractors that provide services for urban Section 5309 and 5307 funded systems that serve populations of 200,000 or less and Section 5311 rural systems. All other safety-sensitive contractors must meet the same standards for compliance as the grantee/subrecipient.

Consequently, grantees/subrecipients must oversee their contractors to ensure compliance. The regulation does not specify the nature or extent of oversight efforts. The regulation gives wide latitude to grantees/subrecipients to take whatever actions they deem necessary to ensure their contractors' compliance. There is a wide array of oversight methodologies in practice within the industry reflecting the financial, political, and operational environment of each unique grantee. Some systems provide technical assistance, policy review and training, others conduct desk reviews using compliance checklists, while still others conduct periodic mock audits. All of these methods and many others are acceptable and represent a wide range of associated administrative burden and cost.

A common misconception among grantees/subrecipients is that the oversight requirements can only be met by conducting periodic, labor intensive, and costly mock audits. Some agencies have felt compelled to hire additional staff to address the resultant workload. This level of oversight is not a requirement of the regulation. Even though an aggressive program of mock audits and intensive oversight is commendable and offers a high level of compliance assurance, other less costly methods may be as effective.

The *Best Practices Manual: FTA Drug and Alcohol Testing Program* discusses contractor oversight and provides examples of contractor oversight checklists (Section 4.2 and Appendix C). These checklists can be used to document oversight efforts and identify areas that require corrective action.

The most successful oversight programs are ones based on a positive relationship between grantee and contractor where the two parties work together to ensure compliance. Often grantees offer resource materials, employee, supervisor and management training, and technical assistance to their contractors. Contractors can be included in the grantee's random pool and piggyback onto the grantee's contracts with service agents. It is also common for grantees to assist contractors in establishing record keeping procedures and preparation of MIS reports. Each of these low cost/no cost efforts are acceptable oversight techniques and improve the grantee's level of assurance that contractors are in compliance.

Oversight programs that successfully identify problem areas and initiate corrective actions will enhance the integrity of each contractor's testing program, minimize compliance issues, avoid potential legal conflicts, and improve the overall effectiveness of the program.

Workplace Drug Use Lowest in 14 Years

Quest Diagnostics Incorporated (QDI) recently released its annual Drug Testing Index® (DTI) for 2002. The DTI summarized the results of workplace drug tests performed during the year by QDI, the leading provider of employer drug testing services in the United States. Overall, workplace drug use and specifically, federally mandated safety-sensitive employee drug use continued its steady decline resulting in a fourteen year low in 2002. In 2002, the positive rate for federally mandated drug tests for all testing categories was 2.5 percent. The decline was across all test types and drug categories. A similar decline was experienced in the positive rate for all workplace testing dropping from a 1988 high of 13.6 percent to a 2002 low of 4.4 percent. The general workforce, experienced a seventy percent rise in amphetamine use since 1998 reflecting an increase in production and trafficking, while the federally-mandated workforce amphetamine use remained stable.

Rx & OTC Medications

Documenting Rx/OTC Involvement In Accidents

Investigations of several recent accidents have identified legally obtained and used medications as contributing factors to the cause or severity of the accidents. In previous issues of the newsletter, FTA has encouraged transit systems to develop a policy on the use of prescription (Rx) and over-the-counter (OTC) medication and develop procedures and a training program for implementing the policy. In addition to these recommendations, transit agencies should also identify and document use of Rx/OTC medications in their post-accident investigations.

Any time an initial accident investigation indicates that prescription or OTC drugs could be a contributing factor to an accident, the supervisor/investigator should document the information provided and system management should investigate the claim further by soliciting additional information from the employee. The following information should be sought:

- Name of all Rx/OTC medications taken within the past seven days;
- List of active ingredients;
- Dosage directions (amount and frequency);
- Dosage practice (amount and frequency);
- Time and amount of last dose prior to accident;
- Time and amount of dose prior to the last one;
- Frequency of use in the last seven days;
- Length of time taking medication;
- Expiration date;
- Presence of warning labels;
- Name of individual the prescription was written for, if applicable;
- List of side effects experienced; with explanation of when they appeared/ disappeared;
- Name of prescribing medical practitioner;
- Did the employee discuss the use and potential side effects of the Rx/OTC with their medical practitioner? Can this be verified?
- Was the medical practitioner aware of the employee's safety-sensitive job duties?
- Place of purchase of Rx/OTC and pharmacist's name (if applicable);
- Did the employee discuss the potential side effects of this Rx/OTC with their pharmacist? Can this be verified?
- Was the pharmacist aware of the employee's safety-sensitive job duties?
- Verify the prescription, if applicable.

The procedures followed to collect this information should be well defined and institutionalized into the agency's post-accident investigation and follow-up procedures. The procedures should be sufficient to determine the nature and extent of causal relationship with the precipitation and severity of the accident. The procedures should also be sufficient to document agency Rx/OTC policy violations.

All information obtained should be held to the strictest level of confidentiality and should be treated as medical records. Absent a federal law requiring disclosure, agencies should follow HHS Health Insurance Portability and Accountability Act (HIPAA) rules (45 CFR Part 164) regarding employee authorization, access, transmission, and storage of protected health information.

These records, however, should be made available to the National Transportation Safety Board (NTSB) and FTA upon request as part of an ongoing accident investigation. A sample form is provided in the *Prescription and Over-the-Counter Medication Toolkit* (see article on previous page) to assist with documentation of the information obtained. Legal counsel should be consulted to ensure HIPAA compliance.

Where to Find? .....

Conforming Products List
Evidential Breath Testing (EBT) Devices
July 21, 2000
Federal Register Vol.65
Pages 45419 - 45423
Primary Topic: Conforming Products List (CPL)
Website location: www.nhtsa.gov/people/injury/alcohol

Note: This list will be updated periodically.

Non-evidential Testing Devices
May 4, 2001
Federal Register Vol.66
Pages 22639 - 22640
Primary Topic: Initial Alcohol Screening Devices

Note: This list will be updated periodically.

The information presented on this page should be used to update Chapter 5 of the revised *Implementation Guidelines.*

Resource Materials

Who Should Be Receiving This *Update*?

In an attempt to keep each transit system well informed, we need to reach the correct person within each organization. If you are not responsible for your system's Drug and Alcohol program, please forward this update to the person(s) who is and notify us of the correct listing. If you know of others who would benefit from this publication, please contact us at the following address to include them on the mailing list. This publication is free.

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FTA Office of Chief Counsel: http://www.fta.dot.gov/office/chiefc
FTA Office of Safety & Security: http://transit-safety.volpe.dot.gov
FTA Letters of Interpretation: http://www.fta.dot.gov/library/legal/dral/02toc.htm
DHHS-Certified Laboratories: http://www.workplace.samhsa.gov/ResourceCenter/lablist.htm
Center for Substance Abuse Prevention: http://prevention.samhsa.gov

FTA, Office of Safety and Security: (202) 366-2896

Best Practices Manual: FTA Drug & Alcohol Testing Program
Drug and Alcohol Consortia Manual
Drug and Alcohol Testing Results: 1995, 1996, 1997, 1998, 1999 and 2000 Annual Reports
Random Drug Testing Manual
Implementation Guidelines for Drug and Alcohol Regulations in Mass Transit, Revised 2002
Reasonable Suspicion Referral for Drug and Alcohol Testing (Leaders' Guide & Video)
FTA Drug and Alcohol Program Assessment
Prescription and Over-The-Counter Medications Toolkit

USDOT Drug and Alcohol Documents FAX on Demand: 1 (800) 225-3784
USDOT, Office of Drug and Alcohol Policy and Compliance: (202) 366-3784

Urine Specimen Collection Procedures Guideline
Substance Abuse Professional Guidelines

Produced by:	Published by:	Edited by:	Illustrated by:
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