

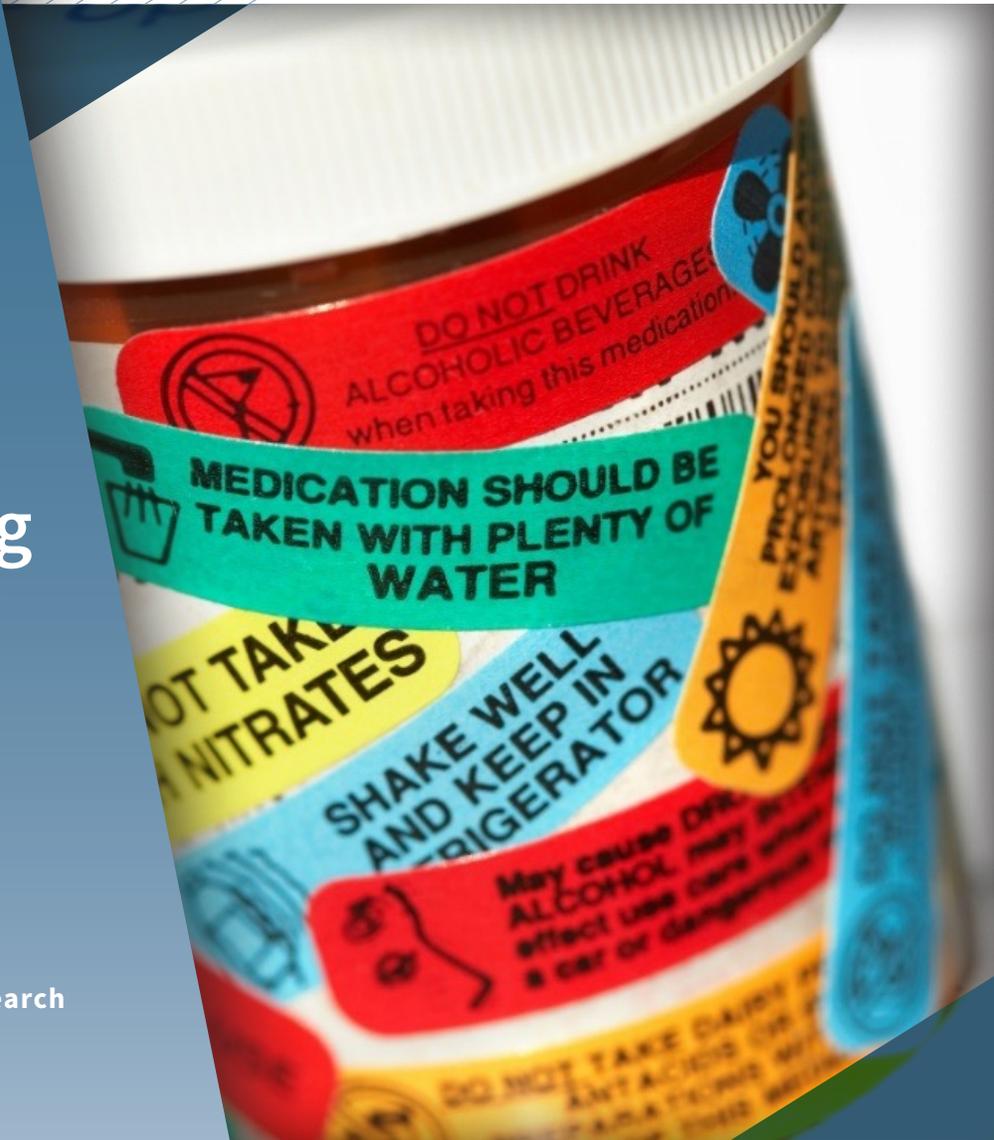
**FTA Standards
Development
Program:
Over-the-
Counter and
Prescription Drug
Use in the Public
Transit Industry**
Final Report

PREPARED BY

Center for Urban Transportation Research



U.S. Department of Transportation
Federal Transit Administration



JUNE
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**FTA Standards
Development Program:
Over-the-Counter and
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Final Report

JUNE 2022

FTA Report No. 0217

PREPARED BY

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Metric Conversion Table

SYMBOL	WHEN YOU KNOW	MULTIPLY BY	TO FIND	SYMBOL
LENGTH				
in	inches	25.4	millimeters	mm
ft	feet	0.305	meters	m
yd	yards	0.914	meters	m
mi	miles	1.61	kilometers	km
VOLUME				
fl oz	fluid ounces	29.57	milliliters	mL
gal	gallons	3.785	liters	L
ft³	cubic feet	0.028	cubic meters	m ³
yd³	cubic yards	0.765	cubic meters	m ³
NOTE: volumes greater than 1000 L shall be shown in m ³				
MASS				
oz	ounces	28.35	grams	g
lb	pounds	0.454	kilograms	kg
T	short tons (2000 lb)	0.907	megagrams (or "metric ton")	Mg (or "t")
TEMPERATURE (exact degrees)				
°F	Fahrenheit	5 (F-32)/9 or (F-32)/1.8	Celsius	°C

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Abstract

This report includes background research and analysis on the need for new standards, recommended practices, guidance documents, or procedural considerations in the areas of prescription (Rx) and over-the-counter (OTC) medication risk management. Gaps that exist in current standards, recommended practices, or guidance documents available to the industry to address Rx/OTC use are identified, and findings are included that address the development or issuance of voluntary standards, protocols, guidelines, or recommended practices related to Rx/OTC risk management and associated topics.

Executive Summary

The Federal Transit Administration (FTA) directed the Center for Urban Transportation Research (CUTR) to research specific focus areas of transit safety risk in support of FTA's standards program. The research program leverages the findings and recommendations of FTA's Safety Standards Research Report, other US Department of Transportation (DOT) research reports and guidance, research performed under the Transportation Research Board (TRB) Transit Cooperative Research Program (TCRP), and other transit-related sponsored research. CUTR uses a Transit Standards Working Group to add locally-based content to the background research, provide guidance and suggestions to the research team, and assist in framing the final background research report and associated findings. This focus area report serves as an addendum to the focus area report *Medical Fitness for Duty and Fatigue Risk Management*. The specific research objectives include:

- Perform background research and analysis on need for new standards, recommended practices, guidance documents, or procedural considerations in the areas of prescription (Rx) and over-the-counter (OTC) medication risk management.
- Identify gaps that may exist in standards, recommended practices, or guidance documents available to industry to address Rx/OTC use.
- Present findings to FTA for its consideration related to the development or issuance of voluntary standards, protocols, guidelines, or recommended practices related to Rx/OTC risk management.

The Moving Ahead for Progress in the 21st Century Act (MAP-21) and its successor, the Fixing America's Surface Transportation (FAST) Act, prompted FTA to establish the Safety Management System (SMS) framework as the basis for its National Public Transportation Safety Program (49 U.S. Code (U.S.C.) Section 5329). SMS is a formal, top-down, organization-wide approach to managing safety risk and ensures the effectiveness of the transit agency's safety risk mitigation. SMS includes systematic procedures, practices, and policies for managing risks and hazards."¹

Title 49 Code of Federal Regulations (CFR) Part 673 requires that each transit agency establish and implement an SMS, appropriately scaled to the size, scope, and complexity of the agency, that includes the following elements:

- Safety Management Policy (SMP)
- Safety Risk Management (SRM)
- Safety Assurance (SA)
- Safety Promotion (SP)

¹ *Federal Register*, Vol. 83, No. 139, July 19, 2018, Pg. 34428, 49 C.F.R. Part 673, Public Transportation Agency Safety Plan Final Rule. § 673.5, Definitions.

SMS brings management and labor together to build a safety culture in transit dedicated to controlling and reducing risk and detecting and correcting safety issues in their early stages. This data-driven approach aids in developing Corrective Action Plans (CAPs) to address safety concerns and establishes safety goals, safety performance targets, and safety performance indicators. These metrics are used to measure the effectiveness of risk mitigations, and CAPs are monitored to ensure the organization is achieving the intended outcomes.

Numerous National Transportation Safety Board (NTSB) accident investigations have indicated Rx/OTC medication impairment as a contributor to transportation safety events and associated injuries and fatalities. In 1990, NTSB published *Fatigue, Alcohol, Other Drugs, and Medical Factors in Fatal-to-the-Driver Heavy Truck Crashes*, a study that recognized the need for standardized post-accident toxicological specimen collection, testing, and reporting.² NTSB has not wavered from the findings of the 1990 study, including recommendations for “a national drug testing standard for passenger vehicles and stronger screening and toxicology testing in commercial transportation”³ in its accident investigation reports. In addition, NTSB recommendations associated with Rx/OTC management have been issued across US DOT modal administrations. However, the risk of impairment-related events continues to remain an area of concern. NTSB included ending substance abuse impairment in the transportation industry in its *Most Wanted List of Safety Improvements* in 2015 and this topic remains an area of concern through its latest *Most Wanted List* in 2022.

Standardization can also improve other Rx/OTC policies and procedures. For example, a Medical Review Officer (MRO) may issue a Significant Safety Concern based on an employee’s legal use of a prescribed medication that is likely to impact the employee’s ability to perform their job functions safely (herein referred to as a Medication Safety Concern). When the MRO issues a Medication Safety Concern, employees have up to five business days from the date of a verified negative test result to have the prescribing physician contact the MRO to determine if the medication can be changed or if it does not pose a significant safety risk. There is no current federal guidance in place to determine how an employer is required to respond to a MRO safety concern. The research team contacted several transit agencies and CUTR’s Transit Standards Working Group members to request information how they respond to a MRO’s significant safety concern notification; results of this additional data gathering effort are presented herein. Through examination of current guidance and regulations, a literature review, and subject matter expert guidance, the following findings were developed.

² https://www.nts.gov/safety/safety-recs/RecLetters/H90_55.pdf.

³ <https://www.nts.gov/Advocacy/mwl/Pages/mwlfs-19-20/mwl5.aspx>.

- **Finding 1:** There has been limited research and industry guidance about the impacts of Rx/OTC medication use by safety-sensitive employees other than effects on revenue vehicle operators. Rx/OTC research may lead to improved internal transit agency policies and procedures, collective bargaining agreements, and reduced Rx/OTC related safety events.
- **Finding 2:** Rx/OTC medication use data that is not routinely collected during safety event investigations. Recognition of the negative effects of Rx/OTC use and the collection of Rx/OTC medication use in safety event investigations may provide additional data for more robust SMS hazard and mitigation analyses and lead to safety event reductions.
- **Finding 3:** Standards do not currently exist to aid transit agencies in responding to the receipt of a medication safety concern reported by an MRO following an FTA-authorized drug test. Development of guidance or standards may reduce agency policy variations and improve safety outcomes through nationally consistent protocols.
- **Finding 4:** Periodic fitness-for-duty evaluations for all employees performing safety-sensitive duties (not just operators) could pro-actively identify an employee's medical condition and/or medication use that may pose a significant safety concern.
- **Finding 5:** The current HHS drug testing panel does not include all potentially driver impairing medications. Expansion of the DOT/FTA drug testing panel to include the benzodiazepines drug class may aid in identifying a safety-sensitive employee's use of potentially dangerous prescription drugs such as diazepam and alprazolam. An employee's use of a legally-prescribed benzodiazepine would be subject to the MRO Significant Safety Concern reporting process for medication use.
- **Finding 6:** Employer policies that require all safety-sensitive employees to report the use of Rx/OTC medication identified as potentially driver impairing (PDI) may reduce risks posed by their use. This may lead to a reduction in impairment-related fatality or injury events.

Section 1

Introduction

The FTA entered a cooperative agreement with the CUTR at the University of South Florida to research areas of transit safety risk, identify existing standards and recommended practices addressing those areas of risk, and perform gap analyses to establish the need for additional standards, guidance, or recommended practices to support and further the safe operation of the nation's public transportation industry. This FTA research report is an addendum to the focus area report *Medical Fitness for Duty and Fatigue Risk Management*. This FTA research leverages the findings and recommendations of FTA's Safety Standards Research Report, other DOT research reports and guidance, research performed under the TRB TCRP, and other transit-related sponsored research. CUTR's Transit Standards Working Group provided locally-based content to the background research, provided guidance and suggestions to the research team, and assisted in framing the final background research report and associated findings.

Section 2

Background Research

Employees who perform safety-sensitive duties should maintain an adequate level of alertness proportionate to the specific stimulus relative to specific operational duties to allow for timely reactions necessary to avoid accidents and incidents. Impairment puts employees at risk of being unable to perform safety-critical duties, endangering their own safety and the safety of others. Impairment can be caused by numerous factors, including but not limited to the use, abuse, or misuse of Rx and OTC medications.⁴ NTSB has recognized and investigated the issue of operator impairment due to medication for over 20 years, with subsequent NTSB recommendations issued to all transportation modes.⁵

This research includes an examination of existing regulations addressing Rx/OTC medications issued by FTA, other US DOT modal administrations, and state DOTs, including State Safety Oversight Agencies (SSOAs). Additionally, this research examines guidance documents, research reports, agency policies, and NTSB recommendations issued in investigation reports where Rx/OTC medication use was determined to be a causal or contributing factor.

The project team used several sources of standards, guidelines, and recommended practices from which to draw content, including the following:

- FTA's Safety Standards, Strategic Plan, and Data Collection Project
- Recommendations from NTSB to FTA, public transportation agencies, and other US DOT modal administrations
- Reports and any associated recommendations to other US DOT modal administrations, such as the Federal Motor Carrier Safety Administration (FMCSA), the Federal Railroad Administration (FRA), and the Federal Aviation Administration (FAA)
- Research reports issued by TRB, TCRP, the University Transportation Centers (UTC) Program members, the Government Accountability Office (GAO), and other research bodies (including state DOTs)
- Voluntary standards and recommended practices in use by the US transit industry, such as recommended practices developed through American Public Transportation Association's (APTA) Standards Program
- Standards, guidelines, and recommendations in use by the Australian Department of Transportation, United Kingdom legislation, and European directives
- State laws and regulations, including those established by Florida, Indiana, and the California Public Utilities Commission (CPUC)
- Transit agency specific policies and best practices

⁴ Federal Railroad Administration, Medical Standards for Railroad Workers, January 2005.

⁵ https://www.nts.gov/Advocacy/mwl/Pages/mwl_archive.aspx.

Literature Review and Policy Summary

The research team performed a literature review of federal regulations, guidance, and recommended practices addressing the use of Rx/OTC medications by vehicle operators in all transportation modes, both within the US and internationally. In addition, the team conducted a comprehensive review of related studies, agency policies, industry standards, and NTSB recommendations linked to the use of Rx/OTC medications. A summary of the literature review is provided below; full regulatory details are provided in Appendix A.

Federal Regulations

Fatal transportation accidents led Congress to find that alcohol abuse and illegal drug use pose significant dangers to the safety and welfare of the Nation. The Omnibus Transportation Employee Testing Act of 1991 (OTETA) was the first federal law to mandate the testing of safety-sensitive transportation employees in the aviation, rail, motor carrier and mass transportation sectors of the transportation industry. Subsequent regulatory revisions have been made as the program has progressed. The federal regulations described in this section are those that are relevant to the discussion surrounding Rx/OTC medication use by safety-sensitive employees.

Title 49 CFR Part 40, Procedures for Transportation Workplace Drug and Alcohol Testing Programs⁶

- US DOT rule that describes the required procedures for conducting workplace drug and alcohol testing for federally regulated transportation industry. The regulation covers all parties who conduct drug and alcohol tests required by USDOT agency regulations, including transportation employers, safety-sensitive employees, and service agents.
 - 49 CFR Part 40 describes the required steps that the Medical Review Officer (MRO) must take as part of the verification process when determining legitimate medical explanations and the basis for reporting medication safety concerns.
- 40.135 (e) You (the MRO) must also advise the employee that, before informing any third party about any medication the employee is using pursuant to a legally valid prescription consistent with the Controlled Substances Act, you will allow 5 business days from the date you report the verified negative result for the employee to have the prescribing physician contact you to determine if the medication can be changed to one that does not make the employee medically unqualified or does not pose a significant safety risk. If, in your reasonable medical judgment, a medical qualification issue or a significant safety risk remains after you

⁶ http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title49/49cfr40_main_02.tpl.

communicate with the employee’s prescribing physician or after 5 business days, whichever is shorter, you must follow §40.327. If, as the MRO, you receive information that eliminates the medical qualification issue or significant safety risk, you must transmit this information to any third party to whom you previously provided information under §40.327 .

Title 49 CFR Part 655, Prevention of Alcohol Misuse and Prohibited Drug Use in Transit Operations⁷

- The purpose of this regulation is to mandate drug and alcohol testing programs to be implemented by employers that receive financial assistance from FTA to prevent accidents, injuries, and fatalities resulting from the misuse of alcohol and prohibited drugs by employees who perform safety-sensitive functions in transit operations.

Title 49 CFR 219, Control of Alcohol and Drug Use, Subpart B 219.103, Prescribed and over-the-counter drugs⁸

- This regulation requires that all railroads under FRA jurisdiction must not prohibit the use of a controlled substance prescribed or authorized by a medical practitioner if:
 - The treating medical practitioner made a good faith judgment that the use of the substance by the employee at the authorized dosage is consistent with safe performance of the employee’s duties.
 - The substance is used at the dosage prescribed.
 - If the employee is treated by more than one medical practitioner, at least one treating medical practitioner must be informed of all medications to determine consistency with safe performance of duties.

Title 49 CFR 240, Subpart C, Post Accident Toxicological Testing §219.207, Fatality⁹

- This FRA regulation requires that in the case of an employee fatality in an accident or incident, “body fluid and tissue specimens must be obtained from the remains of the employee for toxicological testing.”

Title 49 CFR 240.119 (Engineers) Criteria for Consideration of Data on Substance Abuse Disorders and Alcohol/Drug Rules Compliance¹⁰

- Each railroad is required to include criteria and procedures in their programs to ensure that engineers are certified.

⁷ <https://transit-safety.fta.dot.gov/drugandalcohol/regulations/regulations/49cfr655/49cfr655.pdf>.

⁸ https://www.ecfr.gov/cgi-bin/text-idx?SID=2e7278c9ccc7d6d223faed4d9688eb10&mc=true&tpl=/ecfrbrowse/Title49/49cfr219_main_02.tpl.

⁹ https://www.ecfr.gov/cgi-bin/text-idx?SID=359866581708310ada6c7b867c327d58&mc=true&node=pt49.4.219&rgn=div5#se49.4.219_1207.

¹⁰ http://www.ecfr.gov/cgi-bin/text-idx?SID=a08985f1d3b5c948faa052274ca576c4&mc=true&node=se49.4.240_1119&rgn=div8.

- The criteria state that a person who has an active substance abuse disorder must not be certified as a locomotive engineer, and a certified engineer that is determined to have a substance disorder must be suspended from certification.

Title 49 CFR 242.115 (Conductors) Criteria for Consideration of Data on Substance Abuse Disorders and Alcohol/Drug Rules Compliance¹¹

- Each railroad is required to include criteria and procedures in its programs to ensure that conductors are certified.
- The criteria state that a person who has an active substance abuse disorder must not be certified as a locomotive conductor, and a certified conductor who is determined to have a substance disorder must be suspended from certification.

Title 49 CFR 382, Controlled Substances and Alcohol Use and Testing¹²

- The purpose of this regulation is to establish programs to prevent accidents and injuries resulting from the misuse of alcohol or use of controlled substances by drivers of commercial motor vehicles. The regulation applies to drivers of commercial motor vehicles who are not covered by FTA Rule Part 655 of the same title. Therefore, this regulation is not applicable to transit personnel.
- The regulation outlines the testing circumstances and employer responsibilities. This includes the requirements to educate drivers on the effects and consequences of prohibited drug use and the to issue a policy statement that all drivers of commercial motor vehicles comply with the testing requirements as a condition of employment.

Title 49 CFR 673.29 (a)-(b), Public Transportation Agency Safety Plans, Safety Promotion¹³

- (a) This regulation requires transit agencies to establish and implement a comprehensive safety training program for all agency employees and contractors directly responsible for safety in the agency's public transportation system. Refresher training is required in the training program as necessary.
- (b) This regulation also requires that transit agencies communicate safety and safety performance information throughout the organization. The information conveys the hazards and safety risks relevant to employee's roles and responsibilities and informs employees of safety actions taken in response to reports submitted through an employee safety reporting program.

¹¹ http://www.ecfr.gov/cgi-bin/text-idx?node=49:4.1.1.1.36#se49.4.242_1115.

¹² <http://www.ecfr.gov/cgi-bin/text-idx?rgn=div5;node=49%3A5.1.1.2.25>.

¹³ <https://www.ecfr.gov/cgi-bin/text-idx?SID=92e169ba5ffd2bc430cc2ccf666e248c&mc=true&node=p49.7.673&rgn=div5>.

- These sections of 49 CFR 673 subpart C, Safety Management Systems, were defined as the crosswalk from the previous regulations 49 CFR 659.19 (t) related to the required description of the drug and alcohol program and process used to document program compliance.¹⁴

Title 14 CFR 61.53, Prohibition on Operations during Medical Deficiency¹⁵

- The FAA requires, in operations that require a medical certificate, a person shall not act in any capacity as a flight crewmember while that person is taking medication or receiving other treatment for a medical condition that results in the person being unable to meet the requirements for the medical certificate necessary for the pilot operation.

Title 21 CFR 1308 Schedules of Controlled Substances, especially Part 1308.21, Application for Exclusion of a Nonnarcotic Substance¹⁶

- The Food and Drug Administration (FDA) regulation states that any person seeking to have any nonnarcotic drug that may be lawfully sold over the counter without a prescription excluded from any schedule may apply to the Drug Enforcement Administration (DEA).

Guidance and Recommended Practices

Through a review of various published guidance documents, several recommended practices can be gleaned. The aviation sector leads the transportation industry in the development of published guidance on the topic of Rx/OTC medication use. FAA's publications are listed and described within this section. American Automobile Association (AAA) and FTA have also produced guidance which is summarized here.

In November 2019, FAA, published *What Over-the-Counter (OTC) Medications Can I Take and Still be Safe to Fly?*¹⁷ It contains guidelines on which OTC medications incapacitate the pilot to fly under Title 14 CFR 61.53.

- FAA provides pilots with a checklist of what OTC medications are acceptable while still conforming to safety requirements. Title 14 CFR 61.53 defines the minimum time from last OTC dosage, which is five times the dosage interval., This means if the medicine can be taken every 8 hours, a pilot must not have taken a dose in the past 40 hours to be fit to fly. More details are listed in the “go-no-go” table provided for each medication type.

¹⁴ https://www.transit.dot.gov/sites/fta.dot.gov/files/docs/PTSP_NPRM_SSPP_Side_by_Side.pdf.

¹⁵ https://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/app_process/general/prohibition/.

¹⁶ <https://www.ecfr.gov/cgi-bin/text-idx?rgn=div5&node=21:9.0.1.1.9>.

¹⁷ https://www.faa.gov/licenses_certificates/medical_certification/media/OTCMedicationsforPilots.pdf.

FAA Guide for Aviation Medical Examiners, Pharmaceuticals (Therapeutic Medications) Do Not Issue—Do Not Fly¹⁸

- This guidance provides lists of example medications that, if consumed, should result in denial of clearance to fly. The list includes many Rx medications and any OTC medication with a warning label that indicates the possibility of inducing drowsiness or to use caution while operating a motor vehicle.

FAA Pilots and Medications (October 2018)¹⁹

- This video informed industry that impairment from medication, particularly OTC medication, was cited in a number of accidents in general aviation. It summarized the 2011 study results from the FAA's CAMI Toxicology Lab, indicating that drugs/medications were found in 570 pilots (42%) from 1,353 total fatal pilots tested. Of those with positive drug results, 511 (90%) were flying under 14 CFR Part 91. The video cites few studies on the effects of OTC medications on pilots.

Safety Study, NTSB/SS-14/01PB2014-108827, Drug Use Trends in Aviation: Assessing the Risk of Pilot Impairment²⁰

- This study used results from extensive post-accident toxicology testing on fatally injured pilots to assess drug use in aviation. By assessing evidence of their drug use prior to flying and the associated potential for impairment, the study addressed a serious aviation safety issue and a growing transportation safety concern.

FAA TV: Medication and Flying (April 2012)²¹

- This video directed FAA covered employees that medications taken shortly before or during flight (especially if the employee is a pilot) may have undesirable effects on flying skills. The skit-based video gives several scenarios where people medicate and then ask the question "Should I fly?"

AAA Foundation for Traffic Safety, Countermeasures Against Prescription and Over-the-Counter Drug-Impaired Driving²²

- This 2018 report delineates the current state of knowledge on countermeasures against Rx/OTC drug-impaired driving. The study includes approximately 60 possible countermeasures for consideration, some of which may be beneficial across all modes of transportation and

¹⁸ https://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/pharm/dni_dnf/.

¹⁹ <https://www.youtube.com/watch?v=NBFaiZjkOnA&feature=youtu.be>.

²⁰ <https://www.nts.gov/safety/safety-studies/Documents/SS1401.pdf>.

²¹ <https://www.faa.gov/TV/?mediaId=448>.

²² https://aaaafoundation.org/wp-content/uploads/2018/04/VTTI_Rx_OTC_FinalReport_VTTI-4.27-complete.pdf.

beyond the transportation sector. For instance, one countermeasure suggests including a symbol or graphic on OTC medication labels that warn of possible impairment. Other cross-cutting countermeasures include education and data recording themes.

FRA's Prescription and Over-the-Counter Policy Toolkit

- This 2016 tool kit presentation provides guidance to safety-critical rail employees regarding the potential for medical conditions, prescription drugs, over-the-counter medications, dietary supplements, and herbal remedies to adversely impact the safe and effective performance of job duties. The regulations pertaining to FRA regulated employees are described and model policy template recommendations are provided.²³

FTA Prescription and Over-the-Counter Medications Tool Kit (April 2011)²⁴

- This tool kit was instrumental in the understanding of the transit agency's best practices related to Rx/OTC medication use in the public transit industry. It provides valuable examples of agency policies and procedures implemented to reduce accidents and injuries due to impairment while performing safety-sensitive functions. Many agency policies are highlighted throughout the report.
- The tool kit provides examples of accident investigation procedure best practices to ensure that the possible contributing factor of impairment due to Rx/OTC medication is considered routinely in all investigations.
- The tool kit also includes example agency forms, training procedures, and other resources for agencies to consider when developing and implementing Rx/OTC medication programs.

State Laws and Regulations

In the examination of state laws and regulations, it was determined that very few states have enacted laws or regulations specific to medication use in transit operations. Described below are the three programs in which such state laws apply.

- California Public Utilities Commission (CPUC) General Order (GO) 143-B²⁵ Section 12.03 defines the safety rules and regulations governing light rail transit in California. GO 143 forbids “the use, possession, or sale of alcoholic beverages, intoxicants, drugs, narcotics, marijuana, or controlled substances by safety-sensitive employees of light rail transit (LRT) systems, when on duty.” It also states that no safety-sensitive employee should

²³ <https://railroads.dot.gov/elibrary/prescription-rx-and-over-counter-otc-medication-training-and-policy-toolkit>

²⁴ https://www.transit.dot.gov/sites/fta.dot.gov/files/docs/RxOTC_April2011.pdf.

²⁵ <https://docs.cpuc.ca.gov/PUBLISHED/Graphics/598.PDF>.

be allowed to go on duty if under the influence or in possession of any medication, including those prescribed by a doctor, “that will adversely affect their alertness, coordination, reaction, response, or safety.”

- Indiana Department of Transportation (INDOT) Medical Qualification Program Supplemental Policy I states that transit employees are responsible for discussing potential effects of any Rx medication with the prescribing medical practitioner and must refrain from performing any safety-sensitive function while impaired.²⁶ This program is part of Indiana’s Rural Transit Assistance Program and requires Section 5311 transit systems to perform additional, employer-authorized drug testing with an expanded testing panel, following qualifying accidents. The most comprehensive policy, this expanded testing panel detects a greater number of drugs than the USDOT’s drug testing panel.
- Florida Department of Transportation, Equipment and Operational Safety Standards for Bus Transit Systems, §14-90.004(2)(h) states that each bus transit system must establish a drug-free workplace policy statement in accordance with 49 C.F.R. Part 32 and a substance abuse management and testing program in accordance with 49 C.F.R. Parts 40 and 655, as amended.

Foreign Regulations and Guidance

In the examination of foreign regulations and guidance related to driving restrictions stemming from the driver’s use of controlled substances and/or the abuse of psychotropic substances the following were reviewed.

- UK legislation, The Drug Driving (Specified Limits) (England and Wales) (Amendment) Regulations 2015²⁷
 - In England and Wales, Section WA(1) and (2) of the Road Traffic Act of 1988²⁸ restrict a person from driving, attempting to drive, or being in charge of a motor vehicle with a specified controlled drug in their body. This amendment adds the specific restriction of amphetamine in the body to the list of prohibited controlled substances. This regulation applies to all types of motor vehicle operators, not just operators of commercial motor vehicles.
- European Directive 2006/126/EC²⁹
 - This directive addresses driver licenses, stating that they should not be issued or renewed “for applicants or drivers who are dependent on psychotropic substances or who are not dependent on such substances but regularly abuse them.”

²⁶ <https://www.indianartap.com/Medical-Qualification>.

²⁷ <https://www.legislation.gov.uk/ukdsi/2015/9780111128824>.

²⁸ <http://www.legislation.gov.uk/ukpga/1988/52/section/5A>.

²⁹ http://www.emcdda.europa.eu/publications/topic-overviews/legal-approaches-to-drugs-and-driving/html_en.

- Australian Road Transport Act 2013, Part 5.1, Alcohol and Other Drug Use³⁰
 - This regulation prohibits any person driving, occupying the driver seat of a vehicle or occupying the seat next to a learner driver who is driving to have drugs, alcohol, or medicines in the person’s oral fluid, blood, or urine. The regulation is applicable to all types of driver license holders, including those required for commercial or for hire services.

NTSB Investigation Report Recommendations

NTSB investigates every civil aviation accident and significant railroad, highway, marine, and pipeline accidents in the United States.³¹ Its 2019–2020 report *Most Wanted List of Transportation Safety Improvements* includes “End Alcohol and Other Drug Impairment in Transportation” and offers NTSB investigation report recommendations associated with this topic.³² Specifically, NTSB recommends that railroad regulators “establish comprehensive toxicological testing requirements to identify the role played by common prescription and OTC medications” and drivers “be aware that not just illegal substances can be impairing, but some prescription and OTC medicines can also affect how you drive.”³³

Although NTSB does not investigate all public transportation safety events, it has investigated and issued recommendations on the use of Rx and OTC drug use in the public transportation industry. The transit industry would benefit from not only adhering to NTSB recommendations directed to their industry but also those issued to other US DOT modal administrations. NTSB recommendations are included in Appendix B.

Industry Guidance and Recommended Practices

Transit Advisory Committee for Safety (TRACS) Working Group 11-02 Report, *Standards and Guidance for Establishing Policies to Govern the Use of Prescription and Over-the-Counter Medications by Safety-Sensitive Transit Personnel*

- TRACS was tasked with providing recommendations to FTA to issue guidance to transit agencies for improving Rx/OTC policies, employee Rx/OTC notification processes, training, and obtaining and maintaining employee reported information in accident/incident investigations. It provides detailed recommendations for developing transit employer Rx/OTC policies.

APTA Recommended Practice for Transit Bus Operator Training - APTA BTS-BO-RP-001-07³⁴

³⁰ <https://www.legislation.nsw.gov.au/#/view/act/2013/18/chap5/part5.1>.

³¹ <https://www.nts.gov/about/Pages/default.aspx>.

³² https://www.nts.gov/Advocacy/mwl/Pages/mwl_archive.aspx.

³³ https://www.nts.gov/Advocacy/mwl/Pages/mwl_archive.aspx.

³⁴ https://www.apta.com/wp-content/uploads/Standards_Documents/APTA-BTS-BO-RP-001-07.pdf.

- This references federal regulations that require drug and alcohol training, include testing protocol, awareness, compliance and administration details, and that all training be documented.

APTA Recommended Practice for Transit Supervisor Training, APTA BTS-BO-RP-002-07³⁵

- This alludes to federal regulations that require supervisor training for drug and alcohol program requirements, including conditions of testing, awareness, compliance and administration, reporting details. Additionally, it recommends that supervisor incident and emergency response training include directions to initiate and expedite drug and alcohol testing.

Agency Policies

Several transit agencies and other organizations have policies to reduce potential risk associated with degraded performance due to the use of Rx/OTC medications. Some policies reviewed as part of this research are provided in Appendix C, and other policy element details were procured through the information shared in FTA's *Prescription and Over-the-Counter Medications Tool Kit*.³⁶

Greater Cleveland Regional Transit Authority (GCRTA)

GCRTA is the largest public transit agency in Ohio and serves the city of Cleveland as well as the surrounding suburbs of Cuyahoga County. GCRTA's Substance Abuse Policy for Safety-Sensitive Employees is in place to ensure that the safest possible transportation is provided to the riding public and to ensure the safety of the work environment for its employees.³⁷ Within that policy, disciplinary consequences for the use of prescription drugs by safety-sensitive employees are delineated in Section 11.5. This includes non-consideration for hire for job applicants who did not notify GCRTA Human Resources (HR) of prescription drug use prior to a positive drug test and provide a "doctor's letter indicating the applicant's ability to perform his/her proposed job duties is not impaired."³⁸ Additionally, current employees are responsible for providing any prescription drug use notification to HR, accompanied by the same doctor notification of ability to perform job duties. Failure to provide such notification may result in discharge of duties. The policy also addresses the employee as the responsible party to be aware of any effects that such drugs may have on the performance of their duties. GCRTA provides a Prescription Drug Disclosure Form for employees to fill out and submit to HR.

³⁵ https://www.apta.com/wp-content/uploads/Standards_Documents/APTA-BTS-BO-RP-002-07.pdf.

³⁶ <https://transit-safety.fta.dot.gov/DrugAndAlcohol/Publications/DocumentInfo.aspx?DocID=223>

³⁷ https://assets.website-files.com/5b853741ce0232c3d2ea46cb/5b897c67d98b18a5868aaa34_SubstanceAbusePolicy-SSE.pdf.

³⁸ *Ibid.*

The agency addresses Rx/OTC medication use as part of its overall post-accident investigation procedures.³⁹ In a survey performed in 2011, GCRTA confirmed that post-accident investigations include correlation among departments regarding Rx/OTC information, and every accident investigation includes queries regarding any Rx/OTC use and feelings of fatigue. However, at the time of the survey, no employee involved in an incident indicated that they were using Rx/OTC medications or felt fatigued.⁴⁰

Indiana Department of Transportation (INDOT)

The INDOT, through its Rural Transit Assistance Program (RTAP), requires all rural transit agencies throughout the state of Indiana to implement a Medical Qualification Policy to address Rx/OTC medication as a supplement to its overall Medical Qualification Program.⁴¹ Indiana RTAP's Supplemental Policy I, Prescription and Over-the-Counter Medication Policy, recognizes that many medications help individuals maintain an acceptable quality of life, while also acknowledging the dangers of complacency about potential risks that medication use can pose on safety-sensitive employees performing safety-sensitive duties. The policy explicitly states the following:

The employee has the responsibility to discuss the potential effects of any Rx medication with the prescribing medical practitioner including its potential to impair mental functioning, motor skills, or judgment. The employee must refrain from performing any safety-sensitive function any time their ability to safely perform their job duties is adversely impacted by the use of a prescription medication. The use or abuse of medications that impacts employee's ability to perform their safety-sensitive duties are strictly prohibited.

The Indiana policy also outlines that the appropriate use of OTC medications is not prohibited, but employees are responsible for understanding the risk of intoxication and must refrain from performing safety-sensitive duties while adversely impacted by medication use. One unique aspect of the Indiana Rx/OTC Policy is the delineation of the employer responsibilities, which includes providing training and information related to the dangers and risks associated with performing safety-sensitive duties while under the influence of Rx/OTC medications. The employer is also responsible for providing medical authorization forms, maintaining confidentiality of all employee medication use, and sending the employee for medical qualification evaluation by a medical determination officer because of an employee's self-referral. Finally, employers are responsible for requesting a non-FTA synthetic opiates drug test under its

³⁹ <https://transit-safety.fta.dot.gov/DrugAndAlcohol/Publications/DocumentInfo.aspx?DocID=223>.

⁴⁰ https://transit-safety.fta.dot.gov/DrugAndAlcohol/Publications/Documents/Substance/RxOTC_Study/RxOTC_Study_2011_08.pdf.

⁴¹ <https://www.indianartap.com/Medical-Qualification>.

own authority as identified in the Medical Qualification Policy and Accident Investigation Procedures.⁴²

Los Angeles County Metropolitan Transit Authority (LA Metro)

LA Metro operates the third-largest public transportation system in the United States, serving the greater Los Angeles California area. The agency addresses Rx/OTC as part of overall fitness for duty in Section 1.4 of HR Policy 29 (see Appendix C for reference). It recognizes that some medical conditions require the use of prescription and OTC medications that can impair an employee's ability to perform assigned duties safely. With the understanding of risk, all employees must:

- Notify their manager or supervisor when they may not be fit for duty due to medication impairment.
- Read medication warning labels and be aware of possible side effects.
- Inform their health care provider of their safety-sensitive duties so the health care provider can determine if medication use would interfere with the safe performance of these job duties.

LA Metro recognizes that not all medications pose a risk of impairment; therefore, its Medication Reporting Form provides a list of medications that do not need to be reported, as shown in Figure 2-1.

	Los Angeles County Metropolitan Transportation Authority WELL-BEING SERVICES	Attachment 1
	One Gateway Plaza, Mail Stop: 99-14-8, Los Angeles, CA 90012 Medical Services Coordination Phone: (213) 418-3122 Fax: (213) 922-3885 MEDICATION REPORTING FORM	
<ul style="list-style-type: none"> ➤ <u>Please note that the following medications DO NOT need to be reported:</u> aspirin, acetaminophen, antibiotics and antimicrobials, birth control pills, hormones, immunizations, vitamins, creams, lotions, ointments, eye drops, inhalers for asthma, loratadine, pseudoephedrine, medications for acid reflux, corticosteroids, diuretics, Viagra, Cialis, and Levitra. ➤ Metro PROHIBITS safety-sensitive employees from taking over-the-counter medications that carry a warning label against <u>operating machinery or equipment while working and for 8 hours prior to duty.</u> 		

Figure 2-1 Medications not requiring reporting to LA Metro

Maryland Transit Administration (MTA)

MTA is a state-operated mass transit administration operating throughout the Baltimore-Washington metropolitan area. MTA's Policy Number 1C1, Over-the-Counter and Prescription Drug Policy, applies to all safety-sensitive employees and defines prohibited behaviors, such as:

- Using Rx medication not legally prescribed for the employee
- Using Rx or OTC medication in excess of the prescribed dosage

⁴² *Ibid.*

- Using any medication that contains alcohol within four hours before performing safety- sensitive functions
- Using any medication that adversely impacts the employee’s ability to perform his/her safety-sensitive job functions.

Additionally, MTA requires all safety-sensitive employees to obtain a completed Rx/OTC Release to Work Form from a physician for each Rx medication prescribed. Employees medically withheld from service must immediately inform their immediate supervisor, and related absences are defined as “sick,” which count as an occurrence in the agency’s absenteeism policy. Appendix C includes the linked 1C1 Policy and the Release to Work Form.

It is the responsibility of the safety-sensitive employee to read all warning labels before selecting OTC medication for use while in working status. Employees also have the responsibility to assess their personal fitness for duty while using Rx or OTC medications and not report for duty or remain on duty while adversely affected by any medication.

The MTA 1C1 Policy also outlines subsequent discipline for violation of the policy, including immediate removal from service, disciplinary action up to and including termination of employment, and re-employment opportunities may be contingent upon participation in the MTA Rehabilitation Program.

Massachusetts Bay Transportation Authority (MBTA)

MBTA is the public agency responsible for operating most public transportation services in the Greater Boston region. MBTA’s Drug and Alcohol Policy and Testing Program is included in the 2011 FTA Prescription and Over-the-Counter Medications Tool Kit.⁴³ The policy applies to every person who performs a safety-sensitive function for MBTA, including contracted employees. MBTA requires all safety-sensitive employees to consult with medical operations before using Rx or OTC medications that contain alcohol or other substances that may impair their ability to perform their safety-sensitive duties. A medical operations physician will determine if the use of the medication could impair a person’s ability to perform their safety-sensitive duties adequately. If it is determined that an employee is medically disqualified, their supervisor will be immediately notified. Safety-sensitive employees who fail to report the use of potentially impairing medications to obtain clearance are subject to discipline including discharge.

Off-duty safety-sensitive employees who are unexpectedly called to duty must have the opportunity to acknowledge the use of potentially impairing medication use. MBTA conducts and documents “observations of employee’s

⁴³ https://transit-safety.fta.dot.gov/DrugAndAlcohol/Publications/Documents/substance/RxOTC/RxOTC_April2011_Feb2012_Update.pdf.

physical condition” after every accident, which may potentially lead to the identification of medication impairment. The agency maintains an extensive list of approximately 850 Rx/OTC medications and the conditions under which they may be safely taken while performing safety-sensitive job duties. This allows management to remain fully aware of the restrictions associated with each medication. The list also includes the need for an authorization for use from a prescribing physician. MBTA Rx/OTC Medication Restriction Guidelines can be found starting on page IV-24 of the FTA Prescription and Over-the-Counter Medications Took Kit.⁴⁴ Since the report was published in 2011, MBTA updated its processes to maintain the Medication Restriction Guidelines on the agency’s intranet portal. This update allows employees to report their medications through the portal while at the MBTA clinic, which subsequently provides the employee with the associated restrictions associated with the entered prescription.

Metropolitan Evansville Transit System (METS)

METS is a small urban transit agency that operates in Evansville, Indiana. METS addresses Rx and OTC drug use in its drug and alcohol policy, detailing prescribed drugs that must be reported and approved by a physician and prescription drugs that do not require reporting in respective appendices. Safety-sensitive employees are responsible for reading all OTC medication warning labels and not selecting medications that may impair mental functioning, motor skills, or judgment. METS highly recommends that safety-sensitive employees confer with their physicians regarding the possibility of adverse side effects that may impair job performance. Employees are also required to submit a physician-authorized Medication Approval Form for all medications, and it is the responsibility of the employee to explain their jobs to their medical practitioner to ensure that use of the medication will not interfere with the employee’s ability to perform their necessary duties. The METS Drug and Alcohol Policy can be found on page II-99 of the FTA Prescription and Over-the-Counter Medications Took Kit.⁴⁵

Port Authority of Allegheny County

The Port Authority of Allegheny County, headquartered in Pittsburgh, Pennsylvania, serves the county of Allegheny and bordering portions of surrounding counties. The Port Authority has a medication use and reporting policy in place that applies to all safety-sensitive employees and to non-safety-sensitive employees for which driving is an essential function. The policy explicitly states that Port Authority employees are prohibited from working while taking a medication until the medical department determines that the employee can work. Employees are also responsible for reading all warning

⁴⁴ *Ibid.*

⁴⁵ *Ibid.*

labels of OTC medications prior to use. The Port Authority Medication Use and Reporting Policy is provided in Appendix C. The policy prohibits the use of Rx and OTC medication that:

- Is not legally prescribed for the employee
- Is in excess of the prescribed dose
- Contains alcohol within four hours of performing safety-sensitive job functions
- Adversely impacts ability to perform safety-sensitive job functions.

Port Authority employees must report all medications they take that may cause a safety risk when performing job functions. The policy also lists types of medications that do not need to be reported, including:

- Antibiotics
- Antacids and Ulcer medication
- Antiviral agents
- Anti-fungal agents
- Anti-inflammatory medications
- Erectile dysfunction medications
- Immunizations
- Oral contraceptives
- Steroids
- Topical agents
- Vitamins

Prairie Five Rides

Prairie Five Rides, a rural transit agency that serves Montevideo, Minnesota, provides a Rx/OTC policy in a brochure format for easy reference by employees, as shown on page II-105 of the FTA Medications Tool Kit.⁴⁶ A unique element of the pamphlet is the list of medications of concern if used while performing safety-sensitive work. The list is nuanced as “not all-inclusive and is subject to change,” as shown in Figure 2-2.

⁴⁶ https://www.transit.dot.gov/sites/fta.dot.gov/files/docs/RxOTC_April2011.pdf.

Prescription

Analgesics

Aspirin w/codeine, Codeine, Darvocet, Darvon, Demerol, Dilaudid, Empirin
Compound w/codeine, Levo-Dromoran, Methadone, Morphine, Percocet, Percodan, Soma Compound w/codeine, Talacet, Talwin, Tylenol w/codeine, and Vicodin.

Anti-Motion Sickness

Antivert, Dramamine, Marezine, Phenergan, Transderm-Scop.

Skeletal Muscle

Relaxants

Flexeril, Parafon, Soma.

Tranquilizers & Sedatives

Ativan, Denadryl, Centrax, Compazine, Dalmane, Diazepam, Equani, Halcion, Haldol, Libritabs, Librium, Limbitrol, Paxipam, Phenergan, Prolixin, Serax, Stelazine, Thorazine, Tranxene, Valium, Vlarelase, Xanax.

Antidepressants

Adapin, Amitriptyline, Asendin, Deprol, Desyrel, Elavil, Endep, Etrafon, Limbitrol, Lithium, Ludiomil, Marplan, Nardil, Norpramin, Pamelor, Pamate, Petrofrane, Sinequan, Surmontil, To:franil, Triavil, Vivactil.

Barbiturates

Alurate, Butisol, Dilantin, Mebaral, Nembutal, Pentobarbital, Secobarbital, Seconal, Sedapap, Tuinal.

Over-the-Counter

Benadryl, Bromfed, Chlortrimeton, Comtrex, Contac, Deconamine, Dimetapp, Dristan, Drixoral, Extemdryl, Fedahist, Ibuprofen, Kmonfed, Naldecon, Nolamin, Novafed, Omade, Phenergan, Rondec, Rynatan, Sinubid, Sinulin, Sudafed, Tavist-D, Tylenol.

Figure 2-2 *Prairie Five Rides medications of concern if used while performing safety-sensitive work*

The Rx/OTC policy applies to safety-sensitive employees and provides employees with four specific steps to follow when prescribed medications:

1. Advise prescribing physician of the safety-sensitive nature of job duties.
2. Provide prescribing physician with the required Medication Approval Form.
3. Advise physician of any side effects experienced with any past prescription medication.
4. Submit the completed Medication Approval Form, including physician indication of permission or lack of permission to perform safety-sensitive functions.

If deemed unfit to perform safety-sensitive functions while on a temporary medication, the employee is placed on the sick list.

The OTC section of the policy warns employees to take extreme caution when using OTC medication by reading all warning labels before selecting the medication. Specifically, if the warning label indicates that the medication should not be consumed while operating a motor vehicle or may cause drowsiness, the employee is directed/encouraged to select a different medication for use while performing safety-sensitive duties. Employees are also encouraged to consult with a pharmacist or physician if there is any doubt of possible impairment, leaving ultimate responsibility to the employee to ensure the safety of themselves and others by not taking medications that impair their ability to perform their duties.

Rio Metro Regional Transit District (Rio Metro)

Rio Metro is headquartered in Albuquerque, New Mexico and serves as the primary regional transit for Bernalillo, Sandoval and Valencia counties. The Rio Metro's Driver's Code of Conduct prohibits the consumption of narcotic drugs, prescribed narcotic drugs, or OTC drugs that may cause drowsiness or euphoria, induce or prevent sleep, or otherwise dull the senses or reduce reaction time. This applies to employees while on duty and within eight hours prior to reporting to duty. Details can be found on page 15 of the Driver's Code of Conduct in Appendix C.

Southeastern Pennsylvania Transportation Authority (SEPTA)

Serving the greater Philadelphia region, SEPTA's *Drug Free Workplace Manual* (see link in Appendix C) defines the history of the policy, standards of conduct, testing protocol, consequences, education, and treatment options available through its Employee Assistance Program (EAP). SEPTA prohibits the "unlawful manufacture, distribution, dispensing, sale, possession, use, or measurable presence in the body" of drugs or other controlled substances which include but are not limited to OTC medications. The policy specifically states that an employee in a safety-sensitive position must report all potentially sedating medications through the use of a Prescribers Report Form (see link in Appendix C). The submitted form must include the prescriber's recommendation that the medication be used with the understanding of the safety-sensitive nature of the employee's work.

SEPTA also provides a list of prescription drugs and patent medicines. Employees are required to report and disclose use of prescription drugs and patent medicines on the list. The list can be found in Appendix C. Analgesics, anti-motion sickness medicine, tranquilizers and sedatives, antidepressants, barbiturates, and skeletal muscle relaxants are all required to be reported. Additionally, SEPTA do not require that non-prescription cough and cold remedies and antihistamines be reported, but employees should be aware of their potential to induce drowsiness or restrict their ability to perform safety-sensitive duties.

Additionally, SEPTA released a medical department advisory for OTC medications that warns safety-sensitive employees to be aware of the potential drowsy effects that OTC medications may induce. Employees are responsible for reading the warning and ingredient labels of OTC medications to ensure that it will not cause drowsiness or other impairment and that the employee is not taking more than one medicine with the same active ingredient. Specifically, employees are encouraged to check the labels of antihistamines, anti-diarrheals, and anti-emetics. This notice is linked in Appendix C.

TriMet

TriMet, is a public agency operating mass transit in a region that spans most of the Portland, Oregon metropolitan area. TriMet's policy requires safety-sensitive employees notify a supervisor or manager immediately if at any time their fitness for duty is impaired to the extent that their ability to perform any function of their job is threatened. Within SOP 584, Fitness for Duty (linked in Appendix C), operators are responsible for communicating any condition that may impair or intrude upon their ability to perform every essential function of their job safely, including impairment or fatigue due to medically-approved Rx/OTC drugs. TriMet also has a standalone Rx/OTC drug use policy written in a question-and-answer format (see FTA Medications Tool Kit, page II-111).⁴⁷ The policy outlines that safety-sensitive employees must submit approval from the prescribing physician if using a Rx. Detailing the responsibility of determination of fitness for duty lies with TriMet's physician's decision and that employees are responsible for selecting OTC medications that will not interfere with their ability to perform their duties. If a safety-sensitive employee fails to disclose the use of Rx/OTC medication, they are subject to immediate removal from service and disciplinary action up to and including termination of employment.

Washington Metropolitan Area Transit Authority (WMATA)

WMATA is a tri-jurisdictional government agency that operates transit service in the Washington metropolitan area, that include Washington DC, portions of Maryland and northern Virginia. In February 2016, WMATA, revised its Drug and Alcohol Testing Program Policy (7.7.3/4), which contains the policy that WMATA does not prohibit the appropriate use of legally prescribed and OTC medications. However, it does require that safety-sensitive employees must:

- Report the use of OTC medication that may impair job performance, mental function, or motor skills within 72 hours of use or prior to performing safety-sensitive functions, whichever comes first. Employees can report this by completing, signing, and submitting Metro's Prescription Reporting Form to Medical Services. Safety-sensitive employees must also report all OTC medication acquired outside the US.
- Report OTC medication use every 30 days while on the medication.
- Not perform safety-sensitive functions while taking medication with a warning label that states that an individual may not operate a vehicle or dangerous machinery when using such medication.

Agency Policies—MRO Medication Safety Concern Protocol

DOT Rule 49 CFR Section 40.135, Subpart G, Medical Review Officers and the Verification Process,⁴⁸ defines the process that an MRO must follow to

⁴⁷ https://www.transit.dot.gov/sites/fta.dot.gov/files/docs/RxOTC_April2011.pdf.

⁴⁸ <https://www.transportation.gov/odapc/part40/40-135>.

ensure consistency in the verification of lab-confirmed positive test results. The regulation also affords employees a confidential means of presenting a legitimate medical explanation, such as a prescription, for the presence of prohibited drug metabolites detected in their urine. When the MRO verifies an employee's legal prescription for a drug detected by the laboratory, they must report the test result to the employer as negative.

In the event that the MRO believes in their professional opinion that a significant safety concern exists based on the employee's use of a legally-prescribed drug while performing safety-sensitive duties, the MRO must report the significant safety concern to the employer. However, the MRO must allow a period of no more than five days to elapse before reporting the safety concern to the employer. The purpose of the waiting period is to allow the employee's prescribing physician an opportunity to contact the MRO to discuss the employee's use of the medication. The contact must be coordinated by the employee requesting that his/her prescribing physician call the MRO.

When an MRO reports a medication safety concern to an employer, the employer must determine the action that will be taken with respect to the employee's removal from safety-sensitive duty. Additional details related to some of the associated concerns are provided in the Gap Analysis section of this report.

The research team reached out to eight transit agencies to request information regarding how agencies respond to an MRO about a significant safety concern notification. Table 2-1 identifies how the agencies respond to a MRO's medication safety concern report. As illustrated in Table 2-1, agencies are implementing a variety of protocols. These include:

- Three of the eight large transit systems do not remove an employee from safety-sensitive duty upon receipt of an MRO medication safety concern.
- Seven of the agencies do not have a specific written protocol to resolve an MRO-reported medication safety concern.
- 50% of the agencies require a fitness-for-duty exam with a transit agency-designated physician.
- Three of the agencies require the employee to obtain a release from their prescribing physician stating that they can safely perform their duties.
- One agency requires the employee to either obtain a release from their prescribing physician or submit a fitness-for-duty exam.

Table 2-1 Agency Medical Review Officer Safety Concern Response

Agency	Remove from SSD	Policy Specifically Addresses MROSC	Requires FFD Exam w/Agency Physician	Requires Release from Employee's RXP	MRO Communicates with FFD Examiner
LA Metro	Yes	No	Yes	No	No
Tri-Met	Yes	No	No	Yes	No
Port Authority	Yes	Yes	Yes	No	Yes
Houston	Yes	No	Yes	No	No
DART	No	No	Yes	No	No
VTA	Yes	No	No	Yes	No
Orange County	No	No	No	Yes	No
RTD	No	No	Yes	Yes	No

Key: SSD = safety-sensitive duty, MROSC = Medical Review Officer safety concern, FFD = fitness for duty, RXP = prescribing physician

Section 3

Gap Analysis

Based on findings from the background research, review of standards, recommended practices, NTSB recommendations, and stakeholder input, gaps in current guidance and regulations are outlined in the following findings. The findings are related to the need for additional research and guidance related to the impacts of Rx/OTC medication use on safety-sensitive employees who are not operators of commercial vehicles, the inclusion of Rx/OTC information from post-event interviews and post-mortem testing with expanded toxicology panel, guidance for agencies that receive MRO Medication Safety Concern notification, Rx/OTC testing for medical fitness for duty for non-Commercial Driver's License (CDL) employees, the expansion of drug classes to include benzodiazepines and hallucinogens, and requiring the reporting of Rx/OTC drug use.

Medication impairment research tends to focus on vehicle operation only.

In transit operations, safety-sensitive job duties (as defined by 49 CFR Part 655.4) extend beyond the operation of a revenue service vehicle to include controlling movement and dispatch of revenue service vehicles; performing maintenance, repairs, and overhaul on revenue service vehicles; operating ancillary vehicles that require a CDL to operate; and carrying a firearm while performing transit security detail. Safety-sensitive duties such as dispatching and performing vehicle maintenance have a clear bearing on the safe operation of revenue service vehicles and thereby impact public transportation and public safety. However, researchers were unable to identify research reports that address the impact of medication impairment for employees in safety-sensitive positions that do not involve vehicle or equipment operation.

NTD reporting does not specifically collect information on a transit operator's recent use of OTC or Rx medication. To evaluate the extent to which prescription and OTC medication use may have played a role in a reportable accident, employers should interview the operator following an accident and collect data with respect to recent medication use. This data should be captured as part of the accident profile.

FTA does not authorize post-mortem toxicology testing following fatal accidents. Within 49 CFR Part 655 testing requirement clarification, "Whenever there is a loss of human life, each surviving safety-sensitive employee operating the mass transit vehicle at the time of the accident must be tested."⁴⁹ Post-mortem testing should be performed following operator fatalities.

⁴⁹ <https://www.ecfr.gov/current/title-49/subtitle-B/chapter-VI/part-655/subpart-E/section-655.44>.

USDOT’s drug testing panel does not include benzodiazepines. Transit agency employees who perform or could be called upon to perform one or more of the safety-sensitive job duties are covered by the FTA’s “Prevention of Alcohol Misuse and Prohibited Drug Use in Transit Operations,” codified as 49 CFR Part 655, and are thereby subject to US DOT’s “Procedures for Transportation Workplace Drug and Alcohol Testing,” codified as 49 CFR Part 40. The federally-regulated testing program has demonstrated success in deterring prohibited drug use and alcohol misuse in transit operations, but it is limited in its scope and regulatory authority regarding the detection of an employee’s lawfully prescribed medication.

The original crafters of the Omnibus Transportation Employee Testing Act of 1991 were focused on the most predominant “street drugs” of that time. Since 1991, the use and misuse of legally prescribed medication has dramatically increased. According to the National Institute on Drug Abuse, between 1991 and 2013, opioid prescriptions in the US jumped from approximately 76 million to 207 million.⁵⁰ On January 1, 2018, the US DOT testing panel was expanded to include oxycodone, hydrocodone, oxymorphone, and hydromorphone as part of the opioids drug class, which previously included only heroin, morphine, and codeine. The drug classes authorized by HHS to be included in the federal drug testing panel as this report’s publication date are limited to amphetamines, cocaine, marijuana, opioids, and phencyclidine.

There is no federal regulation guiding an employer’s response to medication safety concerns reported by a MRO as a result of a DOT/FTA-required drug test. When a drug or drug metabolite is identified by a Department of Health and Human Services (HHS)-certified laboratory as part of an FTA-mandated drug test, the employee or applicant is provided an opportunity to present a confidential, legitimate medical explanation to a licensed physician, qualified in accordance with the DOT rule to conduct a medical review in accordance with 49 CFR Part 40, Subpart G. This provision introduces two potential areas of concern. First, it is important that specific policies on Rx/OTC address the use of medication and the required notification of medication use by employees. Second, employers are required to determine the best course of action in response to a medication safety concern reported by a MRO, with no current regulatory requirement of action.

During the interview between an employee and a MRO, the laboratory result (drug detected) is compared with the medication the employee reported that they consumed. When the employee’s medication use is validated as lawfully prescribed to them, the result is reported to the employer as a “verified negative” drug test result. However, the MRO has an obligation under USDOT regulation to report to the employer a medication that they feel could pose

⁵⁰ <https://archives.drugabuse.gov/testimonies/2014/americas-addiction-to-opioids-heroin-prescription-drug-abuse>.

a significant safety concern, even when the medication use reported by the donor was not consistent with the drug metabolite detected by the laboratory analysis.

When the MRO determines the existence of a safety concern, they must instruct the employee to ask their prescribing physician to contact the MRO within five business days for the purpose of doctor-to-doctor communication regarding the medication use. Four potential outcomes will follow:

1. During the interview with the MRO, the employee expressly declines the MRO's request to speak with the prescribing physician.
 - MRO response in accordance with Part 40: The MRO will immediately report the medication safety concern to the employer along with the negative drug test result.
2. The prescribing physician does not contact the MRO within the required five business days waiting period.
 - MRO response in accordance with Part 40: The MRO reports the significant safety concern to the employer at the end of the required five-day waiting period. Note: During the five-day waiting period the employer is unaware that a significant safety concern is pending, and the employee remains in safety-sensitive duty.
3. The prescribing physician makes contact with the MRO at some point within the five-business day waiting period. The MRO obtains additional information from the physician regarding the employee's relevant medical condition and/or medication use.
 - MRO response in accordance with Part 40: The MRO has the sole authority to determine if they believe that a significant safety concern exists, even when their medical opinion is contrary to that of the prescribing physician. If the MRO deems that a significant safety concern still exists after discussion with the prescribing physician, they will report the safety concern to the employer immediately following the communication with the prescribing physician.
4. The prescribing physician makes contact with the MRO at some point within the required five business day waiting period. The MRO obtains additional information from the physician regarding the donor's relevant medical condition and/or medication use.
 - MRO response in accordance with Part 40: If the MRO feels that the additional information obtained from the prescribing physician has satisfied their concern, no further action will be taken. The employer is not made aware of the employee's condition and/or medication that the MRO initially felt was cause for concern.

When the employer receives an MRO's safety concern, the employer must determine the best course of action regarding how to resolve the safety

concern. The employer is not currently bound by any regulatory requirement to remove the employee from safety-sensitive duty, nor is there a regulatory requirement for the employer to further assess the employee's medication use in a specific manner. Table 2-1 of this report shows a sample of participating agency responses of how they react upon receipt of a MRO's medication safety concern.

The following are the primary concerns raised by the transit agencies polled in relation to MRO Medication Safety Concerns:

- Up to five days can elapse between the employer's receipt of a verified negative drug test result and the notification that a significant safety concern exists. During that time frame, the employee is performing safety-sensitive duties. Given this delay, employers are concerned about the liability their agencies face in the event of death or injury caused by an impaired employee's actions.
- MROs are given a great deal of discretion to determine when a safety concern should be reported to the employer. In accordance with 40.327, the MRO is to use their "reasonable medical judgement" to make the determination. In the majority of circumstances throughout the US, the MRO interviews the employee over the telephone and has no previous knowledge of the employee's medical history. When contact with the prescribing physician is not facilitated, the MRO is working with very limited information obtained only through a short conversation with the employee.
- Employers requiring an employee to obtain a signed "release" from the employee's prescribing physician are concerned that the prescribing physician often is acting as an advocate for the employee and thereby not evaluating the employee's medication use in an impartial manner.

Summary of Findings

Examination of available background research revealed limited data concerning the impact of Rx and OTC medication use by safety-sensitive employees, beyond revenue vehicle operators. Furthermore, the available resources offer little in the way of mitigation and prevention and are almost exclusively reactive, rather than proactive in their approach. Standards for post-accident data collection may help inform future regulations coupled with fitness for duty evaluations to identify medical conditions and medication concerns in safety-sensitive employees may mitigate safety events. Additionally, employers may benefit from federally mandated actions to resolve MRO Safety Concerns when reported. Lastly, expansion of the DOT drug testing panel to include other drugs of abuse, such as the benzodiazepines drug class, would permit the MRO to verify legal use versus illegal use and report potential safety concerns to employers.

- **Finding 1:** There has been limited research and industry guidance about the impacts of Rx/OTC medication use by safety-sensitive employees other than research about effects on revenue vehicle operators. Further Rx/OTC research may lead to improved internal transit agency policies and procedures, collective bargaining agreements, and reduced Rx/OTC related safety events.
- **Finding 2:** Rx/OTC medication use data is not routinely collected during safety event investigations. Recognition of the negative effects of Rx/OTC use and the collection of Rx/OTC medication use information in safety event investigations may provide additional data for more robust SMS hazard and mitigation analyses that lead to safety event reductions.
- **Finding 3:** Standards do not currently exist to aid transit agencies in responding to the receipt of a medication safety concern reported by an MRO following an FTA-authorized drug test. The development of guidance or standards may reduce agency policy variations and improve safety outcomes through nationally consistent protocols.
- **Finding 4:** Periodic fitness for duty evaluations for all employees performing safety-sensitive duties (not just operators) could proactively identify an employee's medical condition and/or medication use that may pose a significant safety concern.
- **Finding 5:** The DOT/FTA drug testing panel does not currently include all potentially driver-impairing (PDI) medications. Expansion of the panel to include the benzodiazepines drug class may aid in identifying a safety-sensitive employee's use of potentially dangerous prescription drugs such as diazepam and alprazolam. An employee's use of a legally prescribed benzodiazepines would be subject to the MRO medication safety concern reporting process.

- **Finding 6:** Employer policies that require all safety-sensitive employees report the use of Rx/OTC medication identified as PDI may reduce risks posed by their use. This may lead to a reduction of impairment-related fatality or injury events.

Literature Review

The research team performed a review of existing federal regulations and guidance, industry standards, foreign regulations; directions from Australia, the UK, and Europe; and agency policies that focus on the topics described in previous sections. The literature review focused primarily on background information, research reports, and guidance documents related to driver impairment due to Rx and OTC medications. This literature review began with the definitions of Rx and OTC medications and provides key information useful for the purpose of this research study.

Definitions

Prescription Drugs (Rx)

Prescription drugs, often indicated by “Rx,” are substances intended for use in diagnosis, cure, mitigation, treatment, or prevention of specific diseases that are sold only with medical prescription. The symbol “Rx” is the abbreviation of the Latin word “recipe,” which means “to take.”⁵¹ As early as the Middle Ages, pharmacists put this symbol on medicine containers as part of their instructions to patients on when and how often to take the medicine; since then, it has been commonly used to indicate prescription medicines.⁵² With a physician’s prescription, Rx medications can be bought only at a pharmacy and are prescribed for and intended to be used by one person, as regulated by the US Food and Drug Administration (FDA) through the New Drug Application (NDA) process.⁵³ This process is a formal step taken by pharmaceutical manufacturers to request that FDA consider approving a new drug for marketing in the US.⁵⁴ Rx drugs include a label that warns about side effects, such as adverse outcomes if the medicine is taken while operating a vehicle, and are monitored by physicians, who provide advice regarding side effects and safety concerns linked to the intake of the medication. Nonetheless, people still operate vehicles while taking Rx medicines. This can potentially result in accidents and safety concerns, especially if they operate a vehicle to transport passengers.

Over-the-counter (OTC) Medications

FDA defines OTC medications also known as non-prescription medications, as easily found in grocery stores, vitamin stores, and pharmacies.⁵⁵ These

⁵¹ Nix, E. (2018), “Where Did the Rx Symbol Come From?” <https://www.history.com/news/where-did-the-rx-symbol-come-from>.

⁵² *Ibid.*

⁵³ Food and Drug Administration (FDA) (2017), Prescription Drugs and Over-the-Counter (OTC) Drugs: Questions and Answers, <https://www.fda.gov/drugs/questions-answers/prescription-drugs-and-over-counter-otc-drugs-questions-and-answers>.

⁵⁴ *Ibid.*

⁵⁵ FDA, “Understanding Over-the-Counter Medicines,” <https://www.fda.gov/drugs/buying-using-medicine-safely/understanding-over-counter-medicines>.

medications do not require a prescription for purchase and are accessible to most citizens. They can be taken without medical surveillance, and the responsibility of intake is left solely to the patient. For this reason, FDA warns that OTC medicines are safe and effective as long as consumers follow the directions on the label.⁵⁶

Labeling

In March 1999, FDA published OTC Drug Facts label regulations that simplified the OTC label by eliminating words such as “indications,” “precautions,” and “contraindications” that extensive research demonstrated to be confusing and not easily understood by customers.⁵⁷ Until the regulation was issued, information about product directions, warnings, and approved uses appeared in different places on labels depending on the OTC product and brand. Finding information about precautionary actions to take prior to operating a vehicle while taking the medication had been a challenge for those who may be impaired by an ingredient or by the combination of the active principles in a drug product. The new regulation requires that the Drug Facts label on OTC medications should use simple language and an easy-to-read format to help people compare and select OTC medicines; and follow dosage instructions; and precautionary measures to take while taking the OTC medicine and operating a vehicle. According to FDA, the following label information must appear in this order:

- Product's active ingredients, including amount in each dosage unit
- Purpose of product
- Uses (indications) for product
- Specific warnings, including when product should not be used under any circumstances and when it is appropriate to consult with a doctor or pharmacist; and descriptions of side effects that could occur; and substances or activities to avoid
- Dosage instructions, including when, how, and how often to take the product
- Product's inactive ingredients, important information to help consumers avoid ingredients that may cause an allergic reaction.⁵⁸

Along with a standardized format, the label uses plain-speaking terms to describe facts about each OTC drug. For example, “uses” replaces “indications,” and other technical words such as “precautions” and “contraindications” have been replaced with more easily understood words and phrases. The label also requires a type size large enough to be easily read and specific layout details to

⁵⁶ *Ibid.*

⁵⁷ <https://www.govinfo.gov/content/pkg/FR-1999-03-17/pdf/99-6296.pdf>.

⁵⁸ FDA, OTC Drug Facts Label, <https://www.fda.gov/drugs/drug-information-consumers/otc-drug-facts-label>.

improve readability such as use of bullets, spacing between lines, and clearly marked sections.

Drug Facts	
Active ingredient (in each tablet) Chlorpheniramine maleate 2 mg	Purpose Antihistamine
Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: <ul style="list-style-type: none"> ■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy throat 	
Warnings	
Ask a doctor before use if you have <ul style="list-style-type: none"> ■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis ■ trouble urinating due to an enlarged prostate gland 	
Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives	
When using this product	
<ul style="list-style-type: none"> ■ You may get drowsy ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ be careful when driving a motor vehicle or operating machinery ■ excitability may occur, especially in children 	
If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.	
Directions	
adults and children 12 years and over	take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours
children 6 years to under 12 years	take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours
children under 6 years	ask a doctor
Other information store at 20-25° C (68-77° F) ■ protect from excessive moisture	
Inactive ingredients D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch	

Figure A-1 OTC Label example

Following FDA guidelines, all OTC medications on the market include a label that warns about possible adverse effects if the drug is used while operating a vehicle or is taken in combination of other substance. However, many people, intentionally or not, ignore those indications or simply do not read the label. This exposes themselves and other users to the risk of accidents. Similarly, the same situation occurs with prescription drugs.

Rx/OTC Impaired Driving Studies

Impaired driving is generally associated with use and abuse of alcohol and with consumption of illegal drugs. However, the use of legally obtained Rx or OTC medication can also impair driving which endangers drivers, passengers, and other road users. According to AAA, nearly half of all Americans reported taking one or more prescription drugs, 31% reported taking two or more prescription medications, and 11% reported taking three or more prescription medications.⁵⁹ Considering the intake of licit medications while driving, AAA reports that only 28% of drivers consider driving under the influence of prescription drugs a very serious threat; in comparison, 66% consider driving under the influence of alcohol a very serious threat, and 56% consider driving under the influence

⁵⁹ American Automotive Association (AAA), Medication and Driving (Prescription and Over-the-Counter) Fact Sheet, “Drugged Driving.” <https://exchange.aaa.com/wp-content/uploads/2014/12/Prescription-and-Over-the-Counter-Impaired-Driving-Fact-Sheet.pdf>.

of illegal drugs a very serious threat.⁶⁰ Although to a lesser extent, these AAA data are reflected by public transportation employees, especially within those in safety-sensitive positions, as highlighted by NTSB investigations and consequent recommendations to federal agencies.

NHTSA's "Multiple Medication Usage and Driving Functioning" is a study on polypharmacy and driving functioning and includes a literature review on various drugs and their effects on driving.⁶¹ The study found that drivers taking hydroxyzine, a sedating antihistamine, were slower to recognize potential hazards or threats in traffic and slower to apply their brake to stop or slow the vehicle as needed.

"A State-by-State Analysis of Laws Dealing with Driving Under the Influence of Drugs" reviewed statutes regarding drug-impaired driving as of December 2008 and revealed a lack of uniformity or consistency across the states in how they approach drug-impaired driving. Current laws in many states contain provisions that make it difficult to identify, prosecute, or convict drug-impaired drivers due to a lack of distinction between driving under the influence of drugs (DUID) and driving while intoxicated (DWI) arrests and dispositions.⁶² With such inconsistencies, the establishment of data-driven safety improvement guidance is much more challenging. The report called for a need for states to modify their laws to provide separate and distinct sanctions for alcohol and drug-impaired driving.

"Multiple Medications and Vehicle Crashes: Analysis of Databases" analyzed the association of the impairing effects of multiple medication use, drug interactions, and drug disease interactions on motor vehicle crashes in individuals age 50 years and older.⁶³ This study highlighted key aspects of drug interactions when multiple medications are taken simultaneously. The combinations of different drugs have the potential to interfere with metabolism, blood sugar, and other potentially impairing bodily interactions.

"Civil Responsibility for Driving under the Influence of Pharmaceutical Drugs in Germany" focused on civil liability under German law for traffic accidents resulting from the use of medication. Potential defendants of claims for damages, apart from drivers, may include doctors who prescribed the drug and manufacturers of the drugs. The article argues that, from a German law perspective, in many cases it ultimately will make more sense to include the doctor (on a negligence liability theory) and the drug manufacturer (on a strict liability theory) as defendants in an action for damages than merely to consider the obvious perpetrator, the driver.⁶⁴

⁶⁰ *Ibid.*

⁶¹ https://rosap.ntl.bts.gov/view/dot/1843/dot_1843_DS1.pdf?

⁶² <https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/811236.pdf>.

⁶³ <https://rosap.ntl.bts.gov/view/dot/1836>.

⁶⁴ <https://www.ncbi.nlm.nih.gov/pubmed/7666744>.

In February 2015, the Government Accountability Office (GAO) published “Drug-Impaired Driving Additional Support Needed for Public Awareness Initiatives,” a study that investigated drug-impaired driving; and encouraged states to adopt and implement effective programs to reduce driving under the influence of alcohol, drugs, or the combination of alcohol and drugs, including legal use and misuse of OTC and Rx medications.⁶⁵ The study acknowledges that impaired driving is a much broader topic than reductive drunk driving. It also recognizes that drug-impaired driving may be caused by use of illegal drugs, legally-prescribed or OTC drugs that are misused, and some legally-prescribed or OTC drugs even when used as intended. Additionally, citing FDA, the study also determined that although some prescription and OTC drugs can impair driving ability, certain others have no effect or can even enable patients to drive more safely.⁶⁶ The study identified a lack of complete and reliable data on the extent and nature of drug-impaired driving, presenting federal, state, and local agencies with challenges to developing and implementing effective countermeasures. However, it also recognizes that despite limited data and the challenge of defining impairment, federal and state agencies have identified and implemented promising activities such as the Drug Recognition Expert (DRE) Program to combat drug-impaired driving and associated crashes, fatalities, and injuries.

The DRE training program is specifically designed to provide police officers with the tools necessary to recognize impairment in drivers under the influence of drugs other than or in addition to alcohol, such as OTC and Rx medications.⁶⁷ The study recommends that the Secretary of Transportation direct the NHTSA Administrator to identify actions to support state efforts to increase public awareness of the dangers of drug-impaired driving. The effort should be undertaken in consultation with the Office of National Drug Control Policy, HHS, state highway safety offices, and other interested parties as needed and should be conducted in addition to the agency’s current planned efforts.

“State Approaches Taken to Control Access to Key Methamphetamine Ingredient Show Varied Impact on Domestic Drug Labs” investigated how OTC medications can be used to manufacture illicit drugs at home. The research highlights how ingredients of nasal decongestants commonly found in OTC cold and allergy medications can be used to produce methamphetamine, a powerful, highly addictive stimulant drug that has limited medical uses. In addition, it relates ingredients used in OTC and prescription cold and allergy medications to impairment of driving.⁶⁸

⁶⁵ United States Government Accountability Office, “Drug-Impaired Driving Additional Support Needed for Public Awareness Initiatives.” <https://www.gao.gov/assets/670/668622.pdf>.

⁶⁶ *Ibid.*

⁶⁷ Institute of Police Technology and Management, Drug Recognition Expert (DRE) Program. [https://iptm.unf.edu/Drug_Recognition_Expert_\(DRE\)_Program/](https://iptm.unf.edu/Drug_Recognition_Expert_(DRE)_Program/).

⁶⁸ <https://www.gao.gov/assets/660/651709.pdf>.

One action already taken since 2009 by NHTSA to address impaired driving due to drugs other than alcohol is analysis of state laws regarding driving under the influence of drugs.⁶⁹ Many states have supported establishment of Drug Evaluation and Classification (DEC) programs within their state and local police along with the training of special DREs. In addition, because of the overall prevalence of drug use in the US and the growing concern regarding the traffic safety implications of drug use by drivers, 17 states (Arizona, Delaware, Georgia, Iowa, Illinois, Indiana, Michigan, Minnesota, North Carolina, Nevada, Ohio, Pennsylvania, Rhode Island, South Dakota, Utah, Virginia, Wisconsin) have taken the initiative to enact DUID *per se* laws. Neither of these two strategic approaches to the problem of drugged driving (DEC and *per se* statutes) have been widely evaluated for their relative effectiveness. Therefore, NHTSA has commissioned a review of each state statute regarding drugged driving and contacted state officials to discuss these laws.

Conclusions of the report are summarized in a document titled, *A State-by-State Analysis of Laws Dealing With Driving Under the Influence of Drugs*, that provides a comprehensive current analysis of state statutes regarding DUID.⁷⁰ A main finding of the study is a lack of uniformity or consistency in the way the states approach drugged drivers; most do not have separate offense for driving under the influence of drugs, making it difficult to distinguish between DUID and DWI-alcohol arrests and dispositions. In addition, cases in which a driver shows evidence of impairment by multiple substances, the lack of difference in sanctions between drug-impaired and alcohol-impaired driving provides little incentive for criminal justice officials to pursue a drug-impaired driving charge in addition to an alcohol offense. The study also highlights that there is a need for national leadership to develop model statutes and to strongly encourage states to modify their laws to provide separate and distinct sanctions for alcohol- and drug-impaired driving.

The European Community recognized that impairment by misuse and abuse of illicit drugs is a growing problem and conducted several studies, one of which included a European survey on the use of medicines that can impair driving activities. In the study Ravera et al. (2009) identified based on national data, an increasing consumption of antidepressants associated to the augmented intake of Selective Serotonin Reuptake Inhibitor (SSRI), which is responsible for impairment of vehicle operators. The issue is amplified in countries where the drug is obtainable as an OTC medication. However, in these cases, consumption likely has been underestimated. In some European countries, side effects such as temporary incapability to operate a vehicle due to impairment are excluded from the data analysis. The study emphasized the need for future

⁶⁹ <https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/documents/811268.pdf>.

⁷⁰ NHTSA, "A State-by-State Analysis of Laws Dealing With Driving Under the Influence of Drugs." <https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/811236.pdf>.

research that includes improvements to obtain better data and that there should be more harmonization of data collection techniques to establish a reliable epidemiological database. The authors recommended international collaboration to collect data and to propose and implement effective solutions to address impaired driving due to use of licit drugs.

Rx/OTC and Transit

Many US transit agencies address the use, misuse, and abuse of Rx and OTC medications in their policies. Although there is no national guidance on this topic and there is no Rx/OTC medication policy requirement to obtain federal funds, many transit agencies have developed policies that specifically address impairment due to Rx/OTC medications to proactively prevent accidents and injuries and to protect the safety and health of their patrons and employees. Many agencies address the issues and provide guidance to employees on this important topic in their fitness for duty policy, which is required by federal and state laws and regulations.

Some agencies, such as MTA, have established separate policies that provide specific guidance on operator behavior while using licit prescribed or unprescribed drugs. MTA requires employees in safety-sensitive positions to obtain an agency form completed by their physician for each Rx medication prescribed for use while performing safety-sensitive duties. The policy also warns safety-sensitive employees to read the label of OTC medications prior use. In both cases, the policy requires employees in safety-sensitive positions to make the agency aware of their medication use. The complete MTA policy is provided through a link in Appendix C, which also includes a link to a similar policy from the Rio Metro Regional Transit District. Based in New Mexico, Rio Metro's policy includes a short sentence in its driver manual that prohibits the use of narcotics and OTC drugs eight hours prior reporting for duty. Several other agencies have implemented policies and procedures addressing impairment due to illicit drug use; a comparison of those policies is provided in Appendix B, Table B-1.

In 2000, MTA experienced two similar accidents in the same location six months apart, both of which involved the failure of an MTA light rail vehicle to stop at the designated stopping point at the Baltimore-Washington International Airport Light Rail Station. In both cases, according to NTSB,⁷¹ the train struck a hydraulic bumping post apparatus at the end of the track. Investigation of the two accidents indicated that although the direct cause of each accident was different, aspects of the MTA rail transit operation common to the two accidents influenced both outcomes. Consequently, NTSB developed a special investigation report to address the safety factors affecting both accidents.

⁷¹ <https://rosap.ntl.bts.gov/view/dot/14777>.

The investigation determined that the probable cause of one of the accidents was the operator's impairment by illicit and/or prescription drugs, which caused him/her to fail to stop the train before it struck the bumping post at the terminus. NTSB was concerned about the disparity between FTA and FRA regulations concerning substances liable to cause employee impairment. Because FTA regulations do not specifically address the use of Rx/OTC medications by safety-sensitive employees, rail transit operations, unlike railroad operations under the jurisdiction of FRA, may not consider that they have the authority to monitor medication use by safety-sensitive employees.

After investigating accidents for all passenger transportation modes, NTSB recommended that the FMCSA, FTA, and the U.S. Coast Guard (USCG) establish comprehensive toxicological testing requirements for an appropriate sample of fatal highway, railroad, transit, and marine accidents to ensure the identification of the role played by common RX/OTC medications. Additionally, NTSB advised the implementation of a testing revision plan to ensure that such testing is reviewed and analyzed at intervals that do not exceed every five years.

As a consequence of several other investigations, NTSB recommended that administrations with oversight authority on transportation modes establish and implement educational programs for vehicle operators of all transportation modes regarding the hazards of using specific Rx/OTC medications when operating transit vehicles. It has been at least two decades since NTSB presented its first warnings about the negative impacts of Rx/OTC medications on the safety of vehicle operations across transportation modes; these same concerns have been posed and supported in several studies in the field.

Appendix B

NTSB Investigation Reports and Recommendations

A key source available to identify transportation-related risk is the NTSB and recommendations that stem from accident investigations across transportation modes. Table B-1 shows NTSB Rx/OTC-related recommendations and the status of each.

Table B-1 Rx/OTC-related NTSB Recommendations

NTSB Recommendation	General Topic	General Recommendation	Current Status
A-00-004 through 006	Rx/OTC Medications	Establish a list of approved medications and/or classes of medications that may be used safely when operating a vehicle and prohibits use of any medication not on that list except in certain situations.	N/A
R-00-004	Rx/OTC Medications	Establish, in coordination with USDOT, FMCSA, FTA, and the U.S. Coast Guard (USCG), comprehensive toxicological testing requirements for an appropriate sample of fatal highway, railroad, transit, and marine accidents to ensure identification of the role played by common Rx/OTC medications.	Closed – Acceptable Action
R-00-006	Rx/OTC Medications	Develop and periodically publish an easy-to-understand source of information for transit vehicle operators on hazards of using specific medications when operating transit vehicles.	Closed – Acceptable Action
R-00-007	Rx/OTC Medications	Establish and implement an education program targeting transit vehicle operators that, at a minimum, ensures that all operators are aware of the source of information described in R-00-6 regarding the hazards of using specific medications when operating transit vehicles.	Closed – Acceptable Action
R-00-008	Rx/OTC Medications	Establish, in coordination with USDOT, FMCSA, FRA, and USCG, comprehensive toxicological testing requirements for an appropriate sample of fatal highway, railroad, transit, and marine accidents to ensure the identification of the role played by common Rx/OTC medications.	Closed – Acceptable Action
I-00-001	Rx/OTC Medications	Establish, in coordination with FMCSA, RFA, FTA, and USCG, comprehensive toxicological testing requirements for an appropriate sample of fatal highway, railroad, transit, and marine accidents to ensure the identification of the role played by common Rx/OTC medications.	Closed – Unacceptable Action
R-01-025	Rx/OTC Medications	Authorize and encourage rail transit systems to require employees in safety-sensitive positions to inform the rail transit system about their use of Rx/OTC medications so the system can have qualified medical personnel determine the medication's potential effects on employee performance.	Closed – Acceptable Action
H-00-014	Rx/OTC Medications	Establish and implement an education program targeting highway vehicle operators that, at a minimum, ensures that all operators are aware of the source of information described in Safety Recommendation H-00-13 regarding hazards of using specific medications when driving.	Closed – Unacceptable Action

NTSB Recommendation	General Topic	General Recommendation	Current Status
H-00-015	Rx/OTC Medications	Establish, in coordination with USDOT, FRA, FTA, and USCG, comprehensive toxicological testing requirements for an appropriate sample of fatal highway, railroad, transit, and marine accidents to ensure the identification of the role played by common Rx/OTC medications.	Closed – Unacceptable Action

Some key recommendations are highlighted in more detail, with the recipient of the recommendation and links to the investigation reports included. The following recommendations were made to various US DOT modal administrations and other groups in response to NTSB investigation findings related to OTC and Rx medications:

- NTSB Safety Recommendation; in reply, refer to A-00-4 through A-00-6 regarding a 1995 Arnaudville, LA, Cessna 150 accident** – In this letter, NTSB recommended the USDOT to establish a list of approved medications and/or classes of medications that may be used safely when operating a vehicle and to expressly prohibit the use of any medication not on that list except in certain situations. NTSB recommended USDOT modal administrations (FAA, FMCSA, FRA, FTA, USCG) to establish procedures by which modal vehicle operators who medically require substances not on USDOT’s list of approved medications may be allowed, when appropriate, to use those medications while operating a vehicle. Finally, NTSB recommended that FDA establish and require the use of a clear warning label for medications that may interfere with an individual’s ability to operate a vehicle.
- Safety Recommendation R-01-025** – In 2000, MTA experienced two similar accidents in the same location just six months apart. Both accidents involved the failure of an MTA light rail vehicle to stop at the designated stopping point at the Baltimore-Washington International Airport Light Rail Station. NTSB’s investigation of the two accidents indicated that, although the direct cause of each accident was different, aspects of the MTA rail transit operation common to the two accidents influenced both their outcomes. Therefore, NTSB issued a recommendation to FTA to authorize and encourage rail transit systems to require their employees in safety-sensitive positions to inform the rail transit system about their use of Rx/OTC medications so the rail transit system can have qualified medical personnel determine the medication's potential effects on employee performance.⁷²
- Safety Recommendation R-00-004 to FRA** – Establish, in coordination with USDOT, FMCSA, FTA, and USCG, comprehensive toxicological testing requirements for an appropriate sample of fatal highway, railroad, transit, and marine accidents to ensure the identification of the role played by

⁷² https://www.nts.gov/safety/safety-recs/_layouts/ntsb.recsearch/Recommendation.aspx?Rec=R-01-025.

common Rx/OTC medications. Review and analyze the results of such testing at intervals not to exceed every five years.⁷³

- **Safety Recommendation A-00-005** – NTSB has investigated many accidents in all passenger transportation modes in which the use of a licit medication by a vehicle operator has been causal or contributory. As a result, NTSB previously recommended that various agencies take certain actions to address issues pertaining to the use of medications. NTSB's recommendation to FAA was to develop and then periodically publish an easy-to-understand source of information for pilots on the hazards of using specific medications when flying. NTSB's recommendation to FTA was to establish, with assistance from experts on the effects of pharmacological agents on human performance and alertness, procedures or criteria by which transit vehicle operators who medically require substances not on USDOT's list of approved medications may be allowed, when appropriate, to use those medications when operating transit vehicles.⁷⁴
- **Safety Recommendation R-00-006 to FTA** – Develop and then periodically publish an easy-to-understand source of information for transit vehicle operators on the hazards of using specific medications when operating transit vehicles. This recommendation was issued in response of the accident occurred on June 20, 1998, in which a 47-passenger motor coach operated by Greyhound Lines, Inc., struck the back of a parked tractor-semitrailer, which was pushed forward and struck the left side of another parked tractor-semitrailer. Of the 23 people on board the bus, the driver and 6 passengers were killed; the other 16 passengers were injured. The two occupants of the first tractor-semitrailer were injured, and the occupant of the second tractor-semitrailer was uninjured. The probable cause of this accident was the bus driver's reduced alertness resulting from ingesting a sedating antihistamine and from his fatigued condition resulting from Greyhound scheduling irregular work-rest periods.⁷⁵
- **Safety Recommendation R-00-007 to FTA** – Establish and implement an education program targeting transit vehicle operators that, at a minimum, ensures that all operators are aware of the source of information described in R-00-6 regarding the hazards of using specific medications when operating transit vehicles. This recommendation was issued in response of the accident described in Safety Recommendation R-00-006 above.⁷⁶
- **Safety Recommendation R-00-008 to FTA** – Establish, in coordination with USDOT, FMCSA, FRA, and USCG, comprehensive toxicological testing requirements for an appropriate sample of fatal highway,

⁷³ http://www.nts.gov/investigations/AccidentReports/_layouts/nts.gov/recsearch/Recommendation.aspx?Rec=R-00-004.

⁷⁴ https://www.nts.gov/safety/_layouts/nts.gov/recsearch/Recommendation.aspx?Rec=A-00-005.

⁷⁵ https://www.nts.gov/safety/safety-recs/_layouts/nts.gov/recsearch/Recommendation.aspx?Rec=R-00-006.

⁷⁶ https://www.nts.gov/safety/safety-recs/_layouts/nts.gov/recsearch/Recommendation.aspx?Rec=R-00-007.

railroad, transit, and marine accidents to ensure the identification of the role played by common Rx/OTC medications. Review and analyze the results of such testing at intervals not to exceed every five years. This recommendation was issued in response of the accident described in Safety Recommendation R-00-006 above.⁷⁷

- **Safety Recommendation I-00-001** – NTSB has investigated many incidents in all passenger transportation modes in which the use of a licit medication by a vehicle operator has been causal or contributory. As a result, it previously recommended that various agencies take certain actions to address issues pertaining to the use of medications. NTSB recommends to USDOT to establish, in coordination with FMCSA, FRA, FTA, and USCG, comprehensive toxicological testing requirements for an appropriate sample of fatal highway, railroad, transit, and marine accidents to ensure the identification of the role played by common Rx/OTC medications. Review and analyze the results of such testing at intervals not to exceed every five years.⁷⁸
- **Safety Recommendation H-00-014 to FMCSA** – Establish and implement an education program targeting highway vehicle operators that, at a minimum, ensures that all operators are aware of the source of information described in Safety Recommendation H-00-13 regarding the hazards of using specific medications when driving.⁷⁹
- **Safety Recommendation H-00-015 to FMCSA** – Establish, in coordination with USDOT, FRA, FTA, and USCG, comprehensive toxicological testing requirements for an appropriate sample of fatal highway, railroad, transit, and marine accidents to ensure the identification of the role played by common prescription and over-the-counter medications. In addition, NTSB recommends also to review and analyze the results of such testing at intervals not to exceed every five years.⁸⁰

⁷⁷ https://www.nts.gov/safety/safety-recs/_layouts/nts.gov/recsearch/Recommendation.aspx?Rec=R-00-008.

⁷⁸ https://www.nts.gov/investigations/AccidentReports/_layouts/nts.gov/recsearch/Recommendation.aspx?Rec=I-00-001.

⁷⁹ http://www.nts.gov/investigations/AccidentReports/_layouts/nts.gov/recsearch/Recommendation.aspx?Rec=H-00-014.

⁸⁰ https://www.nts.gov/safety/_layouts/nts.gov/recsearch/Recommendation.aspx?Rec=H-00-015.

Agency Policies

Maryland Transit Administration, Over the Counter and Prescription Drug Policy

<https://usf.box.com/s/8glryfyyogbap5h1qsk5k67cw2h5qc70>

Rio Metro Regional Transit District Driver Manual

<https://usf.box.com/s/i2wpqsn0nmryt3ar3kapkxqhwi7kmc6w>

LA Metro Fitness for Duty Policy

<https://usf.box.com/s/40k3cyly9t05hqoptmrylky0cjyazud>

Port Authority

<https://usf.box.com/s/l38hw81kfp6hgnrqk7woj2jf4w0h3yyp>

SEPTA OTC Advisory

<https://usf.box.com/s/ibcawxqrh7358ks4k7w0alhe9jle0kke>

<https://usf.box.com/s/eh5eirrlxnrfelr7bhr91mr2j7uvxkwp>

<https://usf.box.com/s/y0ng4xa83zm57wxi1kmcytrc0a4ly14d>

<https://usf.box.com/s/8ffiiaw8h9w511mbeo2375l2es0pmmr8>

TriMet

<https://usf.box.com/s/9ghvvg2aqb876w8xvslawd1pv67t6hii>

WMATA

<https://usf.box.com/s/yu2lzocqu7q0rmqz9i8vuh9wps4cdj5s>

<https://usf.box.com/s/45uumninwed1aolj8g6ec0vs8yjmiq27>

<https://usf.box.com/s/b6q8xdlgm0zxcwng0znrij5vanifpvqy>

<https://usf.box.com/s/latynmeke1pwmr5k6rowewcdyoxz3apo>



Acronyms and Abbreviations

AAA	American Automobile Association
APTA	American Public Transportation Association
CAMI	Civil Aerospace Medical Institute
CDC	Centers for Disease Control and Prevention
CDL	Commercial Driver’s License
CFR	Code of Federal Regulations
CPUC	California Public Utilities Commission
CUTR	Center for Urban Transportation Research
DART	Dallas Area Rapid Transit
DEC	Drug Evaluation Classification
DRE	Drug Recognition Expert
DUID	Driving Under the Influence of Drugs
DWI	Driving While Intoxicated
FAA	Federal Aviation Administration
FAC	Florida Administrative Code
FAST Act	Fixing America's Surface Transportation Act
FDA	Food and Drug Administration
FDOT	Florida Department of Transportation
FFD	Fitness for Duty
FMCSA	Federal Motor Carrier Safety Administration
FRA	Federal Railroad Administration
FTA	Federal Transit Administration
GAO	Government Accountability Office
GCRTA	Greater Cleveland Regional Transit Authority
GO	General Order
HR	Human Resources
INDOT	Indiana Department of Transportation
LA Metro	Los Angeles County Metropolitan Transit Authority
LETS	Livingston Essential Transportation Services
LRT	Light Rail Transit
MBTA	Massachusetts Bay Transportation Authority
MAP-21	Moving Ahead for Progress in the 21st Century
METS	Metropolitan Evansville Transit System
MRO	Medical Review Officer

MROSC	Medical Review Officer Safety Concern
MTA	Maryland Transit Administration
MVC	Motor Vehicle Crash
NHTSA	National Highway Traffic Safety Administration
NIDA	National Institute of Drug Abuse
NTD	National Transit Database
NTSB	National Transportation Safety Board
ONDCP	Office of National Drug Control Policy
OSHA	Occupational Health and Safety Administration
OTC	Over-the-Counter
PDI	Potentially Driver Impairing
RTD	Regional Transit District
Rx	Prescription Medication
SEPTA	Southeastern Pennsylvania Transportation Authority
SMS	Safety Management Systems
SOP	Standard Operating Procedure
SRM	Safety Risk Management
SSD	Safety-Sensitive Duty
SSOA	State Safety Oversight Agency
SSRI	Selective Serotonin Reuptake Inhibitor
TCRP	Transit Cooperative Research Program
TRACS	Transit Advisory Committee for Safety
TRB	Transportation Research Board
TRI	FTA Office of Research, Demonstration, and Innovation
UK	United Kingdom
US	United States
USC	United States Code
USCG	United States Coast Guard
U.S. HHS	United States Department of Health and Human Services
USDOT	United States Department of Transportation
USF	University of South Florida
UTC	University Transportation Centers
VTA	Santa Clara Valley Transportation Authority

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