■ d. Remove paragraph (c)(3).
■ e. Redesignate paragraphs (c)(4) and (5) as paragraphs (c)(3) and (4), respectively.
■ f. Revise newly redesignated paragraphs (c)(3)(iii), (iv), and (v) and the first sentence in newly redesignated paragraph (c)(4).
■ g. Add paragraph (d).

The additions and revisions read as follows:

§ 202.13 Secure tests.

(a) *General.* This section prescribes rules pertaining to the registration of secure tests or a group of test items prepared for use in a secure test.

(b) * * *

(5) A *test item* is comprised of a question (or ''stem''), the correct answer to that question, any incorrect answer choices (or ''distractors''), and any associated material, such as a narrative passage or diagram, and each item shall be considered one work. A single narrative, diagram, or other prefatory material, followed by multiple sets of related questions and correct or incorrect answers shall together be considered one item.

(c) *Deposit requirements.* Pursuant to the authority granted by 17 U.S.C. 408(c)(1), the Register of Copyrights has determined that a secure test or a group of test items prepared for use in a secure test may be registered with identifying material, and the filing and examination fees required by § 201.3(c) and (d), if the following conditions are met:

* * * * *

(2) In the case of a secure test, the applicant must submit a redacted copy of the entire test. In the case of a group of test items prepared for use in a secure test, the applicant must submit a redacted copy of each test item. In all cases the redacted copy must contain a sufficient amount of visible content to reasonably identify the work(s). In addition, the applicant must complete and submit the secure test questionnaire that is posted on the Copyright Office's Web site. The questionnaire and the redacted copy must be contained in separate electronic files, and each file must be uploaded to the electronic registration system in Portable Document Format (PDF). The Copyright Office will review these materials to determine if the work(s) qualify for an in-person examination. If they appear to be eligible, the Copyright Office will contact the applicant to schedule an appointment to examine an unredacted copy of the work(s) under secure conditions.

(3) * * *

(iii) A copy of the redacted version of the work(s) that was uploaded to the electronic registration system.

(iv) A signed declaration confirming that the redacted copy specified in paragraph (c)(3)(iii) of this section is identical to the redacted copy that was uploaded to the electronic registration system.

(v) In the case of a secure test, the applicant must bring an unredacted copy of the entire test. In the case of a group of test items prepared for use in a secure test, the applicant must bring an unredacted copy of all the test items.

(4) The Copyright Office will examine the copies specified in paragraphs (c)(3)(iii) and (v) of this section in the applicant's presence. * * *

(d) *Group registration requirements.* The Copyright Office may register a group of test items if the following conditions have been met:

(1) All the test items must be prepared for use in a secure test, and the name of the secure test must be identified in the title of the group.

(2) The group may contain an unlimited amount of works, but the applicant must identify the individual works included within the group by numbering each test item in the deposit.

(3) The applicant must provide a title for the group as a whole, and must append the term ''GRSTQ'' to the beginning of the title.

(4) The group must contain only unpublished works, or works published within the same three-calendar-month period and the application must identify the earliest date that the works were published.

(5) All the works in the group must have the same author or authors, and the copyright claimant for each work must be the same. Claims in the selection, coordination, or arrangement of the group as a whole will not be permitted on the application. Each item in the group must be separately copyrightable or must be excluded from the group.

Dated: November 6, 2017.

Karyn Temple Claggett,

Acting Register of Copyrights and Director of the U.S. Copyright Office.

Approved by:

Carla D. Hayden,

Librarian of Congress.

[FR Doc. 2017–24532 Filed 11–9–17; 8:45 am]

BILLING CODE 1410–30–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 40

[Docket DOT–OST–2016–0189]

RIN 2105–AE58

Procedures for Transportation Workplace Drug and Alcohol Testing Programs: Addition of Certain Schedule II Drugs to the Department of Transportation's Drug-Testing Panel and Certain Minor Amendments

AGENCY: Office of the Secretary of Transportation (OST), U.S. Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The Department of Transportation is amending its drug-testing program regulation to add hydrocodone, hydromorphone, oxymorphone, and oxycodone to its drug-testing panel; add methylenedioxyamphetamine as an initial test analyte; and remove methylenedioxyethylamphetamine as a confirmatory test analyte. The revision of the drug-testing panel harmonizes DOT regulations with the revised HHS Mandatory Guidelines established by the U.S. Department of Health and Human Services for Federal drug-testing programs for urine testing. This final rule clarifies certain existing drug-testing program provisions and definitions, makes technical amendments, and removes the requirement for employers and Consortium/Third Party Administrators to submit blind specimens.

DATES: This rule is effective on January 1, 2018.

FOR FURTHER INFORMATION CONTACT: Patrice M. Kelly, Acting Director, Office of Drug and Alcohol Policy and Compliance, 1200 New Jersey Avenue SE., Washington, DC 20590; telephone number 202–366–3784; *ODAPCWebMail@dot.gov.*

SUPPLEMENTARY INFORMATION:

I. Purpose

The Department of Transportation (DOT or the Department) issued a notice of proposed rulemaking (NPRM) on January 23, 2017. 82 FR 7771 (Jan. 23, 2017). The NPRM proposed to revise Part 40 of Title 49 of the Code of Federal Regulations (CFR) to harmonize with certain parts of the revised the Department of Health and Human Services (HHS) Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (HHS Mandatory Guidelines), which was published on

the same day. 82 FR 7920 (Jan. 23, 2017). DOT currently requires urine testing for safety-sensitive transportation industry employees subject to drug testing under Part 40.

There are two changes to the HHS Mandatory Guidelines with which the NPRM proposed to harmonize Part 40. First, the revised HHS Mandatory Guidelines, in part, allow Federal agencies with drug-testing responsibilities to test for four additional Controlled Substances Act (CSA) Schedule II prescription medications: Hydrocodone, hydromorphone, oxycodone, and oxymorphone. Second, the HHS Mandatory Guidelines remove methylenedioxyethylamphetamine (MDEA) as a confirmatory test analyte from the existing drug-testing panel and add methylenedioxyamphetamine (MDA) as an initial test analyte. In addition to harmonizing with pertinent sections of the HHS Mandatory Guidelines for urine testing, the NPRM proposed to clarify certain existing Part 40 provisions; to remove provisions that no longer are necessary (such as obsolete compliance dates); to move the content of certain provisions out of Part 40 and onto the Office of Drug and Alcohol Policy and Compliance's (ODAPC) Web site; and to update definitions and web links where necessary. The Department also proposed to remove existing Part 40 requirements related to blind specimen testing.

The Department received 69 comments on the proposed rulemaking. The comments were from multiple sources including transportation industry associations, drug and alcohol testing industry companies and associations, doctors and medical groups, labor organizations, and individuals.

II. Authority for This Rulemaking

This rule is promulgated pursuant to the Omnibus Transportation Employee Testing Act (OTETA) of 1991 (Pub. L. 102–143, Title V, 105 Stat. 952). OTETA sets forth the requirements for DOT reliance on the HHS Mandatory Guidelines for scientific testing issues. Section 503 of the Supplemental Appropriations Act, 1987 (Pub. L. 100–71, 101 Stat 391, 468), 5 U.S.C. 7301, and Executive Order 12564 establish HHS as the agency that directs scientific and technical guidelines for Federal workplace drug-testing programs and standards for certification of laboratories engaged in such drug testing. While DOT has discretion concerning many aspects of the regulations governing testing in the transportation industries' regulated programs, we must follow the HHS Mandatory Guidelines for the categories of drugs for which we will require testing.

III. Background

Relevant History of the DOT Drug-Testing Program Regulation

The Department first published its drug testing program regulation, 49 CFR part 40 (Part 40) on November 21, 1988 as an interim final rule (53 FR 47002). We based the rule on the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs (See 53 FR 11970, April 11, 1988), which, in part, required cocaine and marijuana to be screened by Federal agencies. HHS based this requirement on the incidence and prevalence of the abuse of these two substances in the general population and on the experiences, at the time, of the Departments of Defense and Transportation in screening their workforces (53 FR 11973–11974). The 1988 HHS Mandatory Guidelines also authorized Federal agencies to test their employees for the use of phencyclidine, amphetamines, and opiates. The DOT published a final rule on December 1, 1989 (54 FR 49854), which incorporated several provisions from the 1988 HHS Mandatory Guidelines. Among these provisions was a 5-panel test that included all of the drugs for which HHS authorized testing. In 1991, Congress passed the Omnibus Transportation Employee Testing Act (OTETA) which, in part, required the Department and DOT Agencies to look to the HHS for the scientific and technical guidelines regarding the drugs for which we test and specimens we collect.

The Department made comprehensive revisions to Part 40 on August 19, 1994 (59 FR 42996), December 19, 2000 (65 FR 79462), and August 16, 2010 (75 FR 49850). The 2010 revision again harmonized our DOT drug-testing program, where necessary, with the HHS Mandatory Guidelines effective October 1, 2010 (73 FR 7185; 75 FR 22809). Specifically, we required initial and confirmatory testing for methylenedioxymethamphetamine (MDMA); confirmatory testing for MDA and MDEA; and initial testing for 6-acetylmorphine (6–AM). We also lowered the initial and confirmatory test cutoff concentrations for amphetamines and cocaine.

Just as we have revised Part 40 in the past, we are revising Part 40 to harmonize, in pertinent part, with the most recently revised HHS Mandatory Guidelines that have an effective date of October 1, 2017. See 82 FR 7920.

Changes Relevant to the HHS Mandatory Guidelines

HHS monitors drug abuse trends and reviews information on new drugs of abuse from sources such as Federal regulators, researchers, the drug-testing industry, and public and private sector employers. In its May 15, 2015 ''Notice of Proposed Revisions'' (See 80 FR 28103), HHS indicated that, since its original HHS Mandatory Guidelines were published in 1988, a number of recommendations had been made for additional drugs to be included in Federal workplace drug-testing programs. According to HHS, recommendations for adding the four semi-synthetic drugs were based on a review of scientific information and on input from the Drug Testing Advisory Board (DTAB) [1] on the methods necessary to detect the analytes of drugs and on drug abuse trends. With the DTAB recommendations, private sector experience findings, and analysis of current drug abuse trends, HHS concluded that the additional semi-synthetic opioids, oxycodone, oxymorphone, hydrocodone, and hydromorphone, should be added in the Federal program.

In its Final Rule dated January 23, 2017, HHS acknowledged that, while it had proposed MDA and MDEA as initial test analytes, three commenters disagreed with the addition of MDA and MDEA as target analytes. HHS indicated that the commenters stated that this change would require modification of current immunoassay reagents, laboratory processes, or both. The commenters noted that this would impose an unnecessary burden for compounds with such low incidence in workplace testing. HHS determined that the number of positive MDEA specimens reported by HHS-certified laboratories does not support testing all specimens for MDEA in Federal workplace drug testing programs. Based on the comments and its own studies, HHS removed MDEA from its Mandatory Guidelines. HHS indicated that it understands MDA and some other analytes also have a low incidence of testing positive, but believes the continued testing for these analytes is warranted in a deterrent program. In particular, inclusion of MDA as an initial and confirmatory test analyte is warranted according to HHS because, in

[1] The Drug Testing Advisory Board provides advice to HHS (the Administrator of SAMHSA) based on an ongoing review of the direction, scope, balance, and emphasis of the Agency's drug-testing activities and the drug testing laboratory certification program. See *http://www.samhsa.gov/about-us/advisory-councils/drug-testing-advisory-board-dtab/board-charter.*

addition to being a drug of abuse, it is a metabolite of MDEA and MDMA.

Harmonizing Changes to the DOT Drug-Testing Program Regulation

In keeping with our obligations under OTETA to follow the HHS Mandatory Guidelines for the drugs for which we test, our NPRM proposed to add and remove the drugs adopted in the revised HHS Mandatory Guidelines for urine testing. Inclusion of these four semi-synthetic opioids is intended to help address the nation-wide epidemic of opioid abuse. Also, adding these four drugs, which are already tested for in many transportation employers' non-DOT testing programs because of their widespread use and potentially impairing effect, will allow the DOT to detect a broader range of drugs being used illegally. This will enhance the safety of the transportation industries and the public they serve. The Department's final rule makes these harmonizing amendments to Part 40.

IV. Main Policy Issues

A. Modification of the Drug Testing Panel

The NPRM

The Department proposed to add the four semi-synthetic opioids to the DOT panel (*i.e.,* hydrocodone, hydromorphone, oxycodone, and oxymorphone) to maintain consistency with the HHS Mandatory Guidelines. Such consistency is mandated by Federal statute, OTETA, and applies not only to the drugs tested but also to specimen testing validity values and initial and confirmatory testing values. To cover these substances, as well as those previously in the opiate category (*i.e.,* codeine, morphine, 6–AM), the NPRM proposed to rename the category from ''opiates'' to ''opioids.''

As we mentioned in the NPRM preamble, opioid abuse and related problems are a major national concern. Transportation industries are not immune to this trend and the safety issues it raises. Consequently, the Department proposed including these substances in its testing panel not only for consistency with the HHS Mandatory Guidelines but as a response to a national problem that can affect transportation safety.

In addition, to be consistent with changes to the HHS Mandatory Guidelines, the Department proposed to remove MDEA from the testing panel and add MDA as an initial test analyte.

Comments

There were 52 comments addressing the addition of the specified semi-synthetic opioids to the DOT testing panel. Of those comments, 41 supported the NPRM's proposal. Supporters generally recognized the need for the Department to act consistently with the HHS Mandatory Guidelines and agreed that addressing opioid abuse issues in the context of transportation safety is important. Of the other 11 comments, several expressed concerns that adding these substances would increase circumstances in which drivers innocently using opioids (*e.g.,* via a prescription for pain medication) would be unfairly treated as drug abusers, with consequent positive tests harming their careers. A few comments suggested adding other substances, such as methadone or synthetic cannabinoids, to the panel.

Other commenters, including some labor organizations, were concerned that employees would have to compromise their medical privacy in order to avoid results being verified positive by medical review officers (MROs). One comment suggested raising the cutoff levels to make it less likely that an employee using a legitimate prescription medication would receive a positive laboratory result. Other comments raised concerns about how adding these opioids to the testing panel would impact other aspects of Part 40, such as MRO determinations about whether a prescription is legitimate or when it is appropriate for an MRO to inform an employer of a safety concern after verifying a negative result based on an employee's legitimate use of prescription medication. Other comments recommended additional rules or guidance concerning MRO practice, such as additional opioids training and directing MROs not to second-guess the prescription judgments of an employee's physician.

DOT Response

We acknowledge the 41 comments that supported adding the four semi-synthetic opiates to the DOT drug testing panel. We agree that this is an important safety improvement. In addition, we appreciate that so many commenters recognized that we must follow the HHS Mandatory Guidelines for the drugs for which we test.

Although a commenter suggested adding other substances and raising the HHS established cut-off levels, we are not permitted to make such changes. As noted above, OTETA requires the Department to conform with the HHS Mandatory Guidelines with respect to the drugs for which we test and their cutoff levels. The Department does not have the discretion to decline to include drugs that are included in the HHS Mandatory Guidelines or to change the cutoff levels that HHS has established. Furthermore, HHS conducted a full notice and comment period regarding these aspects of the HHS Mandatory Guidelines and that time would have been the appropriate point for commenters to request HHS to consider their concerns. To further ensure that our regulated public was kept informed about this opportunity to comment on HHS rulemakings that could potentially affect them, on May 15 and 19, 2015, ODAPC sent notices to the ODAPC list-serve informing subscribers about the HHS proposal so that interested parties could submit comments to the HHS docket. See *http://content.govdelivery.com/accounts/USDOT/bulletins/1047858* and *http://content.govdelivery.com/accounts/USDOT/bulletins/1051d3e.* Once HHS reaches a final determination on the drugs and their cutoff levels, the DOT cannot depart from HHS's decisions on these matters.

Similarly, DOT does not have the authority to add substances such as methadone or synthetic cannabinoids to our drug testing panel without the scientific and technical expertise of the HHS, as expressed in the HHS Mandatory Guidelines. In addition, HHS is limited to testing for drugs under Schedules I and II of the CSA. Parties interested in having additional drugs in those CSA Schedules tested as part of the Federal or DOT program should discuss the matter with HHS.

The Department received comments regarding the relationship between the Department's drug panel and the HHS Mandatory Guidelines during past rulemaking activities. The Department's position, described above, affirms its past responses. (See 75 FR 49850, 49850–49853).

In other sections of this preamble, the Department will discuss comments related to MRO practice issues that could arise when the four new semi-synthetic opioids in our testing panel are introduced. Examples of these issues include an employee's medical privacy, legitimacy of prescriptions, MROs not questioning the treating physician's prescription judgment, and safety concerns.

B. Blind Specimens

The NPRM

The NPRM proposed to remove from Part 40 the requirements for blind specimen testing. The purpose of this proposal was to relieve unnecessary costs and administrative burdens on employers, C/TPAs, and other parties.

The blind specimen requirement has been part of the Department's drug testing program since its inception. The requirement for employers and C/TPAs to submit blinds was intended to help ensure the accuracy of the laboratory testing process. Under the current regulation, an employer will send a blind specimen to an HHS-certified laboratory, accompanied by a Federal Drug Testing Custody and Control Form (CCF) with the name of a fictitious donor, for quality control purposes to see if the laboratory's results match the known contents of that particular blind specimen.

Over the years, as the accuracy of the laboratory testing process was consistently established, DOT reduced the number of blind specimens that employers were required to send to laboratories to reduce cost and administrative burdens associated with the process. As we stated in the NPRM, not one false positive result was found through the testing of the blind specimens in more than 25 years of drug testing.

As the NPRM noted, laboratories are subject to thorough biannual inspections and quarterly proficiency testing through the HHS National Laboratory Certification Program (NLCP). In addition, if an employee has questions about the accuracy of the positive, adulterated, or substituted test result of his or her own specimen, the employee has the right to request the test of his or her split specimen. Believing that the blind specimen testing requirement was no longer necessary to ensure the accuracy and integrity of the testing process, we proposed eliminating this requirement and sought public comment on the subject.

Comments

Twenty-five comments addressed this proposal. Fifteen supported removing the requirement, while ten asked to retain it. Proponents of removal, principally some testing industry associations and employer groups, generally agreed that there were sufficient safeguards on the accuracy and integrity of the system and that blind specimens were unnecessary. They commented that it was, consequently, a good idea to eliminate the costs and burdens associated with the requirement. They said that the accuracy and integrity of the system will not be compromised by eliminating blind specimen testing. One employer association noted that the requirement only affected the largest companies in its industry, and not small businesses.

Opponents of removing the requirement, including labor organizations and some laboratory-related entities, made several arguments. More than one commenter stated that, while the Department may not have been aware of any false positives resulting from blind specimen tests, there was no information presented about the incidence of false negatives. False negatives, they said, could be as damaging to the integrity and safety objectives of the drug testing programs as false positives. Some commenters said the existence of blind specimen testing could provide an incentive to laboratories to maintain the accuracy of their procedures, somewhat analogous to the deterrent effect of random testing on employee behavior. In its absence, laboratories might relax their standards. Other commenters said that, even if blind specimen testing did not reveal any false positives, the existence of the process of blind specimens added to, or at least increased the appearance of, fairness to employees.

In addition, some commenters noted that because laboratories will begin testing for new substances proposed under the NPRM (*i.e.,* the semi-synthetic opioids), it would be useful to maintain blind specimen testing to help to ensure that errors did not occur in the testing of these newly added drugs. Also, some of the commenters believed that it would be better to keep blind specimen testing in place as a safeguard, as opposed to relying wholly on split specimens and the NLCP. One commenter noted that NLCP's oversight of laboratories could be weakened by future decreases in HHS budgets and this could lead to the reduction of the effectiveness of that program.

DOT Response

The history of the blind specimen testing requirement shows decreasing reliance on this process as a safeguard. Laboratories have accumulated a record of accuracy spanning more than 25 years. Years ago, the DOT reduced the amount of blind specimen testing from three percent to one percent, with no known ill effects on the integrity of the process.

We disagree with the commenters who implied that elimination of the blind specimen testing would cause laboratories to change the way they do business and, thereby lower their standards. Given the continuing rigorous HHS oversight and the business necessity of maintaining accuracy, it is not likely that laboratories would relax their standards simply because the relatively small number of blind specimen tests now required has been eliminated.

While commenters who favor retaining the requirement expressed concern about the possibility of false negatives, or the potential loss of a deterrent effect on laboratories by eliminating blind specimen testing, these concerns are speculative. None of the laboratories or blind specimen manufacturers who commented provided data to support any assertions of false negatives. Without data to support these assertions, the Department has no basis on which to substantiate that there are false negatives indicative of systemic laboratory problems. Instead of identifying laboratory problems, false negatives, if they exist, could be attributed to problems with the manufacture of the blind specimens or employers and C/TPAs not adhering to the manufacturer's instructions on the use or expiration date of their product. The Department retention of the blind specimen testing requirement would exacerbate, not reduce, those problems.

The Department and the transportation industries rely upon the NLCP certification and oversight processes, as well as the split specimen testing process, to ensure that the accuracy of the laboratory testing is up to NLCP certification standards. In OTETA, Congress directed the Department to rely on HHS-certified laboratories, without any reference to the additional process of blind specimen testing. Moreover, there have been no false positive results for blind specimens reported to the Department, as required by the current Part 40, either before or after the NPRM was issued. The Department will continue to rely on HHS for laboratory certification because now more than 25 years of blind specimen testing has shown that there have been no false positive blind specimen results.

Given the rigorous HHS oversight of the laboratories, as well as the business necessity for the laboratories to maintain a reliable record of accuracy, it is not likely that laboratories would relax their standards simply because the relatively small number of blind specimen tests now required was eliminated. Consequently, the Department is adopting its proposal to remove blind specimen testing requirements from part 40.

C. The DOT List-Serve

The NPRM

The NPRM proposed requiring key personnel in the drug and alcohol testing process—collectors, Breath

Alcohol Technicians (BATs), Screening Test Technicians (STTs), Medical Review Officers (MROs), Substance Abuse Professionals (SAPs)—to subscribe to the Office of Drug and Alcohol Policy and Compliance (ODAPC) list-serve. That list-serve is a very useful source of information for: The DOT drug and alcohol testing rules and programs; guidance for handling issues that have arisen in the implementation of the program; relevant antidrug information from Federal partners; and updates concerning the program. Subscriptions are free to users. Currently, there are more than 40,000 ODAPC list-serve subscribers.

Comments

Everyone who commented thought that the list-serve is a very useful tool that many of them subscribe to and support. Nine of the 13 comments on this proposal expressed full or qualified support for the proposal to make the ODAPC list-serve mandatory for key persons who have currency requirements included in their part 40 qualification requirements. Opponents of requiring subscription to the list-serve said that the proposed change was unnecessarily prescriptive and could impose compliance costs (*e.g.,* time spent signing up and reading the material) that were not considered in the regulatory evaluation. One commenter stated that subscribing to the list-serve served no safety purpose. In addition, they asked how the requirement could be monitored, documented, or enforced. One commenter offered that the proposal would work better as a ''best practice'' than a mandate. Some commenters supported the proposal because of the useful information the list-serve provides, but had questions and concerns about its implementation. One commenter suggested that supervisors of BATs, STTs, and collectors should be required to subscribe instead of the BATs, STTs, and collectors themselves. This commenter believed that their supervisors should make sure that they learned relevant information conveyed by the list-serve. Another supporter of the proposal was concerned that monitoring staff members' compliance could be burdensome for parties like C/TPAs. Another expressed concern about how the mandate would work given, the rapid turnover of collectors and BATs.

DOT Response

The Department is appreciative that the commenters recognized the value of the list-serve, and that a number of industry organizations expressed their commitment to publicizing the service and encouraging their members to take advantage of it. We want to extend our gratitude to all who have spread the word about the usefulness of the list-serve and to the more than 40,000 subscribers.

As noted in the NPRM, we believe that the cost and burdens of additional drug and alcohol program workers subscribing to the list-serve would likely be minimal, and that there would be benefits to everyone receiving the useful information it contains. While some commenters expressed concern about potential costs, we note that the service is free. Reading information on the list-serve is unlikely to be time-consuming and no different than if the service agent were to receive the information from a different source. Signing up for the list-serve merely requires one to enter one's email address on the Office of Drug and Alcohol Policy and Compliance's Web page at *www.transportation.gov/odapc.* No comments attempted to provide data regarding potential costs.

Since the plain language rewrite of 49 CFR part 40, 65 FR 79462 (December 19, 2000), collectors, MROs and SAPs have been required to ''keep current on any changes to . . . [the applicable regulations and guidelines].'' This applies to collectors in § 40.33(a); Medical Review Officers (MROs) in § 40.151(b)(3); Substance Abuse Professionals (SAPs) in § 40.281(b)(3) [SAPs]. Similarly; § 40.213(a) requires Breath Alcohol Technicians (BATs) and Screening Test Technicians (STTs) to ''be knowledgeable about the alcohol testing procedures in this part and the current DOT guidance.''

DOT agency auditors, inspectors and investigators who inspect the service agents listed above currently ask the individual collector/BAT/STT/MRO or SAP whether that individual is current on 49 CFR part 40 and the applicable guidelines, to ensure the requirements for currency are met. The individual service agent would need to produce a 101-page copy of 49 CFR part 40 and the applicable guidelines in hard copy. After the list-serve requirement becomes effective, the individual service agent may demonstrate currency by showing the most recent list-serve—most likely by displaying it on the service agent's smart phone or other computer. Proving one's subscription to the list-serve will show the DOT auditor/inspector/investigator that the individual is subscribed to a system that provides an opportunity to stay current with the latest information about the program. Unequivocally, this would be a cost savings, would help to improve compliance by getting the relevant and timely information into the hands of the specified service agents, and would demonstrate the DOT's commitment to making information available electronically.

Even when a service agent subscribes to the list-serve, it is a best business practice for that service agent to keep a paper copy of Part 40 and applicable guidelines for easy reference and for when electronic retrieval of these documents is not possible. Certainly, service agents can view these documents on-line at ODAPC's Web site, but Internet accessibility is not always possible, especially during transportation operations in remote areas.

While we would welcome the subscription to the list-serve by management personnel, it would not make sense to put the requirement of a list-serve subscription upon the collection site supervisor or other management personnel because they are not necessarily the individuals responsible for complying with the qualification requirement under the existing Part 40 to remain current in his or her knowledge. A collector/BAT/STT/MRO or SAP is the individual with the requirement for training, remaining current and maintaining his or her own documentation.

The Department disagrees with the comment that subscribing to the list-serve serves no safety purpose. Over the years, we have used the list-serve to inform the DOT-regulated industry about various important program-related information. For example, list-serves have included: Public Interest Exclusion decisions against fake MROs; changes to the Federal Drug Testing Custody and Control Form (CCF) and authorization for use of the electronic CCF (eCCF); updated guidance documents such as: The Urine Specimen Collector Guidelines; What Employers Need to Know About DOT Drug and Alcohol Testing; FAA's Designated Employer Representative videos; FTA's Annual National Drug and Alcohol Conference; Official ODAPC Interpretations of Part 40; and the FMCSA's National Drug and Alcohol Testing Clearinghouse. Each of these notices touched on topics directly related to the DOT's drug and alcohol testing program. The list-serves communicate information that is related to the integrity and safety aspect of the program.

D. MRO Practice Issues

The NPRM

The NPRM proposed to amend existing § 40.141(b) to say that ''prescription,'' for purposes of MRO

verification determinations, means ''a legally valid prescription under the Controlled Substances Act [CSA].'' This same language was used in § 40.135(e), in the context of informing third parties about potential safety implications of an employee's use of a controlled substance. The intent of the proposal was to harmonize the language of these sections for clarity and consistency.

It has always been the intent of this program to follow the CSA regarding what constitutes a legally valid prescription. The term ''prescription'' has become more loosely used in recent years. Under the Internal Revenue Code, individuals can be reimbursed for over-the-counter medications and some services, if the taxpayer has a ''prescription'' from their doctors for these things that are not controlled substances under the CSA. In addition, some state laws allowing marijuana use the term ''prescription,'' even though a recommendation for someone to use marijuana under state law is not a prescription consistent with the Controlled Substances Act.

The NPRM also proposed to allow MROs to conduct additional testing (*i.e.,* for D,L stereoisomers of amphetamine and methamphetamine isomers and/or tetrahydrocannabivarin (THC–V)) of a specimen, if doing so is necessary to verify a test result. The testing for D,L stereoisomers of amphetamine and methamphetamine can be useful to an MRO in distinguishing whether a methamphetamine positive resulted from use of a legitimate over-the counter product. An MRO can order a test for THC–V to be conducted to determine whether the laboratory reported marijuana result was due to the smoking of marijuana. The THC–V differential testing can distinguish whether a THC positive is due to the smoking of marijuana, a CSA Schedule I illegal drug, or is due to the use of Marinol, a CSA Schedule III prescribed pharmaceutical. Because of this regulatory change, MROs do not need to obtain DOT consent to order such tests. However, MROs can use only laboratories that meet NLCP criteria for conducting these additional tests.

Comments

There were only nine comments on these specific proposals. All of them supported the authorization of MROs to order the laboratory to test for D,L stereoisomers of amphetamine and methamphetamine or THC–V. One comment, from a testing industry association, suggested that the Department issue more detailed guidance to MROs concerning when it is appropriate to order these tests. Another comment suggested making the testing for D,L stereoisomers of amphetamine and methamphetamine mandatory in all methamphetamine positives to avoid delays in reporting final verification results to employers.

With respect to the definition of ''prescription,'' eight of the nine commenters supported the NPRM. The ninth suggested that this was a matter better left to medical organizations. Another commenter suggested that the rule specify that there could never be a legally valid prescription for marijuana, to reinforce that state ''medical marijuana'' laws do not have validity for the purposes of the DOT program, which is bound to follow Federal law. One commenter specifically noted that the word ''prescription'' is not specifically defined in the CSA.

As noted earlier in the ''Modification to the Drug Testing Panel'' section, commenters to the proposal to add the four semi-synthetic opioids raised a number of issues concerning MRO practice. One issue of concern to several commenters was whether a prescription should still be considered by the MRO as a legitimate medical explanation if it had been filled a long time before the positive test result (*e.g.,* six months, a year, two years before the drug test that an MRO is being asked to verify). They said this is an important inquiry because the semi-synthetic opioids proposed to be added to the DOT testing panel are Schedule II drugs that are frequently prescribed and may be retained and used by the donor long after the prescription was filled. Some commenters were concerned that MROs' decisions have been and will continue to be inconsistent regarding the age of a prescription considered to be grounds for declaring a legitimate medical explanation for a positive result.

A related comment asked that DOT clarify that an MRO could not question a prescribing physician's decision to issue a prescription. That is, an MRO should not ''second guess'' the prescribing physician's determination that it was medically appropriate to prescribe one of the four semi-synthetic opioids and verify a test as positive notwithstanding the existence of the prescription.

Other commenters recommended that MROs should receive more frequent training than currently required (*e.g.,* requalification training every three years rather than every five years), with special emphasis on issues concerning the semi-synthetic opioids added to the DOT panel. One of these comments suggested that MROs should not be authorized to make determinations about these drugs until they had received specific training concerning the semi-synthetic opioids. This commenter also asked that legal review of MRO decisions be permitted under the regulations and that MROs and collectors themselves be subject to drug testing.

Another area of comment focused upon the provision of § 40.327(a) that directs MROs to report to employers and third parties when safety concerns remain after a non-negative test laboratory-confirmed result is downgraded to a negative due to the existence of a prescription. Some commenters believed that the downgraded non-negative results are still likely to result in the medical disqualification of the employee (§ 40.327(a)(1)), for those positions that require medical qualification, such as airline pilots, Coast Guard mariners and Commercial Driver's License (CDL) drivers. For those without medical certification requirements, these commenters believed that the MRO would report a ''safety concern'' under § 40.327(a)(2) when, in the MRO's medical judgment, the employee's continued performance of his or her safety-sensitive function is likely to pose a significant safety risk. These commenters' concern was that, absent further regulatory language or guidance from DOT, some MROs might report information to employers (*e.g.,* information about a semi-synthetic opioid that an employee was legally taking) from which an employer could infer an employee's medical condition. These commenters believed that release of information would not only compromise the employee's medical privacy but could threaten the employee's job. One commenter thought that paragraph (a)(2) should be deleted altogether. Commenters suggested that, before reporting a safety concern under § 40.327(a)(1), an MRO should be required to contact the employee's prescribing physician to determine whether the physician was aware of the employee's safety-sensitive duties and, if so, whether the prescribing physician believed the prescribed drug would not impair the employee's ability to perform those duties safely.

DOT Response

The Department is adopting the NPRM's proposal to authorize MROs to conduct testing for D,L stereoisomers of amphetamine and methamphetamine and THC–V. Most commenters agreed that these proposals had merit. We do not believe it necessary to make the testing for D,L stereoisomers of amphetamine and methamphetamine mandatory in methamphetamine cases,

believing it better to leave this decision to MROs' discretion. Neither is it necessary to make THC–V testing mandatory. To make these requirements would be unnecessary in most cases and would, therefore, cause needless expense with no additional safety benefit. In response to those who thought additional guidance is necessary, we will provide it in the future on the basis of demonstrated need.

We will also adopt, with a slight change, the NPRM's language saying that a prescription means a legally valid prescription within the overall meaning of the CSA. While, as one commenter pointed out, the CSA does not contain an explicit definition of ''prescription,'' the Drug Enforcement Administration (DEA), which is designated by statute to carry out the CSA, has regulations and guidance regarding prescriptions. Therefore, we are changing the proposed language to say that a prescription must be ''consistent with'' and not simply ''under'' the CSA. The proposed language was already present in § 40.135(e), so we will make a technical amendment to that language for consistency. In addition, we have added the same language to § 40.137(a) to provide clarity to MROs when verifying laboratory-confirmed positive test results.

The key point of the phrase we have added is to make sure that a prescription is legally valid. For example, regardless of any state ''medical marijuana'' laws, there cannot be a legally valid prescription for marijuana, since it remains a Schedule I substance under the CSA.

The issues concerning restricting an MRO's judgment about how long a prescription may be considered to be legitimate are complex and not appropriate for this rulemaking. The Department is concerned that establishing a ''bright line'' cutoff date for the valid use of a prescription—*i.e.,* that an otherwise legally valid prescription would be regarded as no longer providing a legitimate medical explanation for a laboratory positive after a certain amount of time had passed—would be a too-facile substitute for the individualized inquiry that we expect an MRO to make in such cases. It could also result in an unintended hardship on an employee who is not intentionally abusing a prescription medication but who unintentionally runs afoul of a standardized expectation for how quickly he or she will use medication prescribed.

The DEA has not set a maximum duration for the length of time a prescription can be considered to be legally used by the person to whom it was prescribed. Consequently, it would not be appropriate for the Department to substitute its judgment for that of the DEA, which is the Federal agency with the authority for determining what constitutes a valid prescription under the CSA.

The MROs are highly qualified individuals who Part 40 requires to make judgment calls. MROs must take into account differences in medications, and other case-specific factors. While some commenters characterize this as ''inconsistent'' across the breadth of a national program, it carries out the intention that MROs will make individualized determinations for each donor. Although it might be less work and superficially ''consistent'' for MROs to make decisions on the basis of a ''bright line'' standard, doing so would not advance the objectives of the program. Consequently, the Department will not create a time limit on the use of a legally valid prescription.

Some commenters also suggested that the final rule prohibit an MRO from questioning whether the prescribing physician should have prescribed the substance. That is, the MRO should not be allowed to say, in effect, ''yes, the employee has a legally valid prescription issued by his or her physician, but I think that the physician should not have issued that prescription in the first place, or the prescription was for too high a dosage of a drug, so I won't treat the prescription as a legitimate medical explanation for a laboratory positive.'' This situation could arise, for example, with respect to prescriptions for the opioids added to the DOT panel by this rule (or for any other legally prescribed drug identified in our drug panel), if an MRO thought an employee's doctor had been too liberal in prescribing pain medications.

We agree that it is inappropriate for an MRO to question an employee's legally valid prescription in this way. Even if the employee's physician's prescription practices are inconsistent with an MRO's understanding of good standards of medical practice, employees are entitled to rely on their physicians' prescriptions as authorization to use the legally prescribed substance as a legitimate medical explanation. To say otherwise would place an unfair burden on the employee to judge the appropriateness of his or her physician's conduct. As a logical outgrowth of this issue raised by commenters, we have added language to § 40.137 of the final rule to prohibit MROs from denying a legitimate medical explanation because the MRO thinks the prescribing physician should not have prescribed the medication to the donor. However, it is important to note that a valid concern about whether the employee can continue performance safely may be present and the prescribing physician may still be asked to reconsider the employee's use of the prescription in accordance with § 40.135(e).

MROs with a concern about a physician's prescribing practices can address this with the prescribing physician or raise the issue with the appropriate state licensing agency for the prescribing physician. For example, an MRO can choose to file a complaint with a local DEA office, a medical licensing board, or other oversight organization regarding the practices of a prescribing physician who the MRO believes is violating standards of care. That approach remains a more direct way to address the possible malfeasance of the prescribing physician, instead of denying the legitimacy of the safety-sensitive employee's prescription.

The issue of states or nations (*i.e.,* Canada and Mexico) that allow recommendations or state-recognized ''prescriptions'' for ''medical marijuana'' presents a completely different consideration. Marijuana is a Schedule I drug and, therefore, regardless of the prescribing physician's intent, it cannot be the basis of a legitimate medical explanation. Consistent with longstanding DOT regulatory language and guidance (*e.g.,* §§ 40.137(e)(2), 40.151(e), and DOT ''Medical Marijuana'' Notice *https://www.transportation.gov/odapc/medical-marijuana-notice;* DOT ''Recreational Marijuana'' Notice *https://www.transportation.gov/odapc/dot-recreational-marijuana-notice*), MROs must not treat medical marijuana authorizations under state law as providing a legitimate medical explanation for a DOT drug test that is positive for marijuana.

We agree with commenters that MROs should receive appropriate information concerning issues that may arise with respect to the semi-synthetic opioids added to the DOT panel in this final rule. The Department will issue guidance, as needed, highlighting opioid issues that may arise.

We believe that shortening the MRO re-training interval to three years would impose a cost and burden that is unnecessary. Since we already have opiates in the DOT-regulated drug testing panels, adding semi-synthetic opioids to the panel is not a radical change for these highly trained Medical Doctors and Doctors of Osteopathy. Likewise, requiring special training concerning opioids for MROs, or

limiting their ability to verify opioid positive test results unless they had received such training, is likely to unnecessarily delay implementation of the addition of these controlled substances to the program without a justifiable reason to require the training. There was no showing by commenters that, absent such specialized training outside the normal training process, MROs would be incapable of assessing whether there were legitimate medical explanations for opioid positive results. Thus, we believe that additional training is not needed to ensure that MROs are familiar with semi-synthetic opioid issues.

As noted above, commenters were concerned that, as applied to commonly prescribed substances like the semi-synthetic opioids covered by this rule, § 40.327(a)(2) could lead to adverse outcomes for employees such as compromising the employee's medical privacy or employment. For example, an MRO might note that an employee had a legally valid prescription for an opioid, which provided a legitimate explanation for a laboratory positive result, but then decide that the employer should be told that the employee's use of that opioid poses a significant safety risk, endangering the employee's continued employment. Given the apparent frequency with which opioids are prescribed, commenters feared that the occurrence of issues of this kind could increase.

Although we did not propose any new language to § 40.327, we believe this section warrants a discussion and a slight amendment to the existing language of § 40.135 as a logical outgrowth of the commenter's concerns as to the frequency with which medical information would be reported because of adding the four semi-synthetic opioids. It may not be necessary for the MRO to report medical information to third parties in every case where the MRO receives substantiated evidence that an employee has a valid prescription that merits downgrading a result from a positive to a negative.

Under § 40.327, an MRO must report drug test results and medical information the MRO learns as part of the verification process to third parties without the employee's consent if the MRO determines, in his or her reasonable medical judgement, that either of two concerns is triggered. First, the MRO is required to disclose to third parties information when the information obtained during the verification interview is likely to render the employee medically unqualified under an applicable DOT agency regulation (*e.g.,* a fitness for duty requirement). Second, the MRO must report the information to third parties if the ''information indicates that continued performance by the employee of his or her safety-sensitive function is likely to pose a significant safety risk.'' The third parties to whom this information can be disclosed are: The employer; a DOT agency; a SAP; or an examiner who determines whether the employee is medically qualified under an applicable DOT agency safety regulation.

We understand, and the commenters were concerned, that MROs already apply the procedures of §§ 40.135 and 40.327 to commonly prescribed medications that can cause a laboratory-confirmed positive result. Thus, adding the semi-synthetic opioids would pose a similar, but certainly not a new, scenario of a laboratory-confirmed positive that would be downgraded to a negative result because of a legally valid prescription, and this medical information would be reported to a third party, when appropriate.

This concern, however, should not be overstated. There is not an automatic requirement for an MRO to report medical information to third parties for every downgraded drug test result. There are and will continue to be cases where the MRO would not need to report medical information to a third party. We leave the determination of the significant safety risk to the ''reasonable medical judgment'' of the MRO, recognizing that every downgraded test result is not the same and needs the individualized professional judgment of the MRO.

The MROs have a serious safety duty when verifying the prescription an employee provides to the MRO. Under § 40.141(b), the MRO (and not the MRO's staff) must ''review and take all reasonable and necessary steps to verify the authenticity of all medical records the employee provides.'' With the advancement of photography manipulation and enhancement software easily available through the Internet, MROs should speak with the pharmacy and not simply rely on a photograph of the prescription label. That contact with the pharmacy can also shed light on whether there is a significant safety risk posed in the particular situation the MRO is assessing.

To ensure that the employee is not caught by surprise by an MRO's decision to report the medical information regarding a legally valid prescription to a third party, we have amended § 40.135(e). Specifically, we will direct the MRO to first provide the employee with up to five business days after the reporting the verified negative result to have the prescribing physician contact the MRO to determine if the medication(s) can be changed to one that does not make the employee medically unqualified or that does not pose a significant safety risk before reporting the safety concern. If the MRO does not receive such information from the prescribing physician, the MRO would then report to third parties as provided in § 40.327. The provision of giving the employee five days to have his/her prescribing physician contact the MRO is not new. In fact, it has been in part 40 since the year 2000. The only difference is that previously, the MRO would first report the medical information and then wait for the prescribing physician to respond. We have no reason to believe this process is not effective. However, in response to the commenters' concerns, we are changing this process to provide the employee the opportunity to allay any MRO safety risk concerns by having his or her prescribing physician change the medication immediately, discuss other ways to eliminate or mitigate the MRO's concerns, or both change the medication and discuss alternatives. This should also reduce the number of reports MROs would make. We do not anticipate this change will increase costs because there is no new collection of information, we are simply directing the MRO to pause for five days before reporting the medical information to third parties. In fact, this pause may reduce costs because we anticipate that it should reduce the number of reports to employers under § 40.135(e).

Although we are creating a pause before the MRO reports the information so that the employee can have time to communicate with the employee's own physician, the part 40 requirement for the MRO to report the downgraded test result as a verified negative immediately remains unchanged. With this final rule, the employer will receive a negative result first and medical information, if necessary, will come later.

There may be cases where the MRO is contacted by the employee's physician before the end of the five days, but the communication between the doctors does not alleviate the significant safety risk that the MRO has identified. In such cases, the MRO can report the medical information to third parties after the discussion with the employee's physician; the MRO is not required to allow five days to elapse.

Comments that MRO decisions should be legally reviewed and that MROs and collectors should be subject to drug testing are outside the scope of this

rulemaking. Thus, they will not be addressed.

E. Fatal Flaws and Questionable Specimens

The NPRM

The NPRM proposed to add three fatal flaws to the existing list of four flaws that would cause a test to be cancelled. Each fatal flaw is an error that cannot be subsequently corrected because of the potential for each of the flaw to affect the accuracy and integrity of that specimen. The existing fatal flaws are listed in §§ 40.83 and 40.199. The proposed additional flaws were listed in a September 2016 revision of the HHS NLCP Manual. Specifically, the flaws proposed to be added were: (1) There is no CCF; (2) two separate collections were performed using one CCF; and (3) there was no specimen submitted to the laboratory with the CCF.

The NPRM also addressed a situation when there is an initial ''questionable'' specimen (*e.g.,* one calling for an immediate recollection under direct observation because the temperature was out of range or there were signs of tampering), but there was no second specimen provided (*e.g.,* because the donor was unable to provide the second specimen under direct observation, even after waiting three hours and drinking fluids). The current regulation does not provide clear instructions to the collector regarding what to do with the initial specimen in this scenario. The NPRM proposed that the collector discard the initial specimen in this case, leaving the MRO to determine whether there was a sufficient medical explanation for the ''shy bladder.''

Comments

One commenter noted that the changes to fatal flaws by the NLCP, the source of the Department's proposed changes, had not earlier been the subject of public comment before HHS changed the HHS Mandatory Guidelines in this respect. This commenter also noted that there could be inconsistencies between HHS and DOT criteria for fatal flaws.

Another commenter raised a technical point with respect to the proposed § 40.83(c)(2), requesting clarification to say that a CCF without an accompanying specimen would become a fatal flaw only when an actual specimen had been collected. The commenter explained that, in a shy bladder or collection site refusal situation, a collector might mistakenly send a CCF to the laboratory, even when there was no specimen to send. If the test were cancelled by the laboratory, then there would be no shy bladder evaluation and, what may have been a refusal would result in a cancelled test. Two other commenters, also referred to this same situation, saying that the solution would be to clarify that this fatal flaw exists only when a specimen was actually collected.

With respect to the ''questionable specimen'' scenario on what to do with a first specimen that was collected and was out of temperature range or showed signs of tampering, but then a sufficient second specimen was not collected under direct observation, we received ten comments. All of these comments on the proposal supported it.

DOT Response

Three commenters who were concerned about a fatal flaw cancelling a test in the ''insufficient specimen'' scenario raised a good point related not only those scenarios, but also for collection site walk-away refusals. The Department will adopt these commenters' suggestions that a fatal flaw will exist in cases where a CCF is sent to the laboratory without a specimen, as long as there a specimen was actually collected. This will avoid a situation in which, for example, there was a CCF filled out for an original specimen, a shy bladder situation occurred, no second specimen was collected, but the CCF was mistakenly sent to the laboratory. The ultimate result of this process—a determination by the MRO about whether there was a sufficient medical explanation for the employee's failure to provide a full specimen—could be confused by a laboratory decision that there was a fatal flaw, even though the fatal flaw has no impact upon the MRO's determination of a refusal. Accordingly, we have amended §§ 40.83 and 40.199, both of which deal with this particular fatal flaw.

Otherwise, the Department is adopting its proposal with respect to fatal flaws without change. Commenters had the opportunity to comment on these proposed changes in context of the DOT NPRM, whether or not HHS provided such an opportunity concerning its changes to the HHS Mandatory Guidelines.

Regarding the ''questionable specimen'' scenario, the DOT is adopting the proposed amendment to Part 40 without change. All commenters agreed that, when a second specimen in a situation calling for a recollection under direct observation cannot be obtained for ''shy bladder'' reasons, it made sense to discard the first questionable specimen and rely on the insufficient specimen process for a result. In the insufficient specimen process, an MRO with advice from a referral physician determines whether there was a refusal to test or not. This approach of discarding the insufficient specimen is simple and direct, and should reduce opportunities for confusion. It is also a cost-relieving provision.

V. Section-by-Section Analysis

This portion of the preamble discusses each of the provisions of Part 40 amended by this final rule, including responses to comments on matters that have not previously been discussed under ''Main Policy Issues.''

A. Sections Concerning the Addition of Four Opioids to the DOT Drug Testing Panel

In the ''Main Policy Issues'' portion of the preamble, we discussed the proposal to add four semi-synthetic opioids to the DOT drug testing panel and responded to comments on that proposal. As noted there, the Department is adopting this proposal. The primary section in which the Department's decision to add these substances is carried out is § 40.87, which lists each substance that is part of the DOT panel, including the additions made by this final rule, together with the initial test and confirmatory test cutoffs. There are parallel changes in § 40.85(d) and Appendices B and C, in each case changing the term ''opiates'' to ''opioids.'' A commenter suggested rewording the proposed language in § 40.87, footnote 3, to match the language in the HHS Mandatory Guidelines. After discussing this point with HHS, we changed the wording from what was proposed to a more accurate and plain language version, with no intended change in meaning. In §§ 40.137 and 40.139, a slightly different term, ''semi-synthetic opioids,'' is used in the contexts of differing standards for MRO verification of ''natural'' opioid laboratory positives (*e.g.,* codeine) and the newly added semi-synthetic opioids to the DOT drug testing panel (*e.g.,* hydrocodone).

B. Definitions

The final rule, like the NPRM, clarifies the definition of ''The Department, DOT Agency'' and ''Drugs.'' The main change in the latter is to use the broader term ''opioids'' in place of ''opiates,'' to encompass the substances that the rule adds to the DOT drug panel. There were few comments on the proposed changes to this section.

One commenter requested that we clarify that NASA or its contractors were not DOT agencies. As readers of the existing and new versions of this

section will note, NASA is not listed as a DOT agency. As a Federal agency, NASA is subject to the Federal employee program that uses the HHS Mandatory Guidelines. Contractors to or employees of NASA or other Federal agencies who are subject to DOT regulations in their own right (*e.g.,* because they perform safety-sensitive functions as pilots, drivers or mariners who would be covered by the respective applicable DOT agency regulations) would be covered by applicable DOT rules.

We also included a technical amendment to this section based on a recent official interpretation. Specifically, we are clarifying that the USCG is only a DOT agency for the drug testing component of Part 40 since its regulation (46 CFR part 16) incorporates Part 40 for drug testing and not for alcohol testing.

C. Three Provisions Related to Urine Specimens

Fatal Flaws

The rationale for the Department's decision to add new items to the list of ''fatal flaws'' and our response to comments on the proposal to do so, are found in the ''Main Policy Issues'' portion of this preamble. The affected provisions are §§ 40.83(c) (concerning fatal flaws detected by a laboratory as it processes a specimen) and 40.199 (concerning the MRO's responsibility to cancel tests in which fatal flaws have been found).

Shy Bladder Process—''Questionable Specimens''

As discussed under the Fatal Flaws and Questionable Specimens heading in the Main Policy Issues portion of this preamble, after considering the comments on the subject, the Department will require the collector to discard any initial collection that was questionable (*e.g.,* out of temperature range, showing signs of tampering). The MRO would then evaluate a ''shy bladder'' situation that developed if the employee was unable to provide a sufficient specimen for the direct observation recollection. This provision has been incorporated into § 40.193(b)(4).

Only Urine Specimens Are Authorized for Testing

The NPRM proposed to add a new section, § 40.210, clarifying, that Part 40 authorizes drug testing of only urine specimens screened and confirmed at HHS-certified laboratories. This means that point-of-collection instant tests, hair tests, and oral fluid tests are not presently allowed under Part 40 for DOT drug testing. There were four comments on this proposal, all of which agreed with it.

The Department is aware that a rulemaking that would authorize oral fluid testing under the HHS Mandatory Guidelines is currently in progress at HHS. If HHS authorizes this method of testing, DOT could follow on with its own rulemaking to conform Part 40 to the revision of the HHS Mandatory Guidelines, as long as the HHS final rule is in accordance with OTETA's other requirements.

Likewise, it is our understanding that HHS is considering whether to authorize hair testing as part of the HHS Mandatory Guidelines. As in the case of oral fluids, and given the Department's statutory obligation to remain consistent with the HHS Mandatory Guidelines and with OTETA's other obligations, if HHS authorizes the use of hair testing in a manner consistent with OTETA requirements, then the Department would follow suit in its own rulemaking to amend Part 40.

We are also aware that there are unusual circumstances in which testing other than urine testing can take place. For example, Federal Railroad Administration (FRA) post-accident testing, under the authority of 49 CFR part 219 (not Part 40), can involve blood testing and the testing of other body fluids and tissues. Likewise, the USCG, under the authority of 46 CFR part 4, may require other bodily fluids or tissues be chemically tested to determine the presence or drugs or alcohol for post-accident events. Part 40 recognizes certain situations when a clinical evaluation performed under the direction of the MRO is appropriate, and in those events the MRO may choose to use another testing methodology (49 CFR 40.195(a)(3)). The MRO may use another testing methodology in these narrow situations for the purpose of being able to clarify that a donor is not using drugs, but not to show a positive test result. However, these situations are not inconsistent with the new § 40.210, which states that for drug tests required by Part 40, only urine testing is authorized.

D. Removing the Blind Specimen Testing Requirement

The rationale for the Department's decision to remove the blind specimen testing requirement, and our response to comments on the proposal to do so, are found in the ''Main Policy Issues'' portion of this preamble. As a result of this decision, sections, or references in sections, pertaining to the former blind testing requirement have been removed. The affected provisions are in §§ 40.03, 40.29, 40.37, 40.103, 40.105, 40.123, 40.169, and 40.189.

E. Prohibition on DNA Testing of Urine Specimens

The NPRM proposed adding a sentence to paragraph (f) of this section further emphasizing the existing DOT prohibition on the use of DNA testing on DOT drug testing specimens (§ 40.13(e)). The five commenters who spoke to the proposal supported it. Several comments supported the Department's long-standing grounds for its position (*e.g.,* that the CCF process provides sufficient evidence of the identity of a specimen; that DNA testing would show only that an original specimen and a reference specimen that the donor provided behind closed doors were different, not that a donor's specimen was misidentified). Some commenters added that the prohibition would preclude further intrusions into an employee's privacy and potential discrimination by employers against drivers whose DNA test revealed a potential medical condition. The new language states that DNA testing is not authorized and ODAPC will not give permission for such testing. The Department is adopting the proposed language without change.

F. Legal Prescriptions and Additional Testing

As discussed under the MRO Practice Issues heading in the Main Policy Issues portion of this preamble, the Department proposed to add a reference to legal prescriptions under the CSA to this section, as well as to authorize MROs to obtain THC–V testing and testing for D,L stereoisomers of amphetamine and methamphetamine at their discretion. After considering the comments, almost all of which were supportive, as discussed above, the Department has adopted this proposal with the slight modification of ''consistent with'' instead of ''under,'' and incorporated these changes in §§ 40.137(b) and 40.135(e) for consistency.

G. Minor Modification to Certain Section Headings

The NPRM proposed to modify the section heading of §§ 40.137 and 40.139 to incorporate the addition of the four new semi-synthetic opioids. There were 10 comments on this proposal, all of which agreed with it. The Department is adopting the proposed language without change. Also, as commenters correctly pointed out, and as is discussed under the MRO Practice Issues heading in the ''Main Policy Issues'' portion of this

preamble, the proposed § 40.139(c)(3) should be rephrased. This paragraph should provide that, in a situation where there is a laboratory positive for morphine or codeine (in the absence of a finding of 6–AM) below 15,000 ng/mL, and the employee admits to unauthorized use of one of the semi-synthetic opioids, the MRO does not verify the test as positive. The final rule makes this correction.

H. Subscribing to the ODAPC List-Serve

The rationale for the Department's decision to require key persons in the DOT testing process to subscribe to the ODAPC, and our response to comments on the proposal do so, are found in the ''Main Policy Issues'' portion of this preamble. The Department is adopting the proposed language without change. The affected provisions are §§ 40.33 (collectors), 40.121 (MROs), 40.213 (BATs/STTs), and 40.281 (SAPs).

I. Listing SAP Certification Organizations on ODAPC's Web Site

The NPRM proposed moving organizations who provide SAP credentialing listed in § 40.281(a)(6) out of Part 40 and onto the ODAPC Web site. We proposed this change to provide greater flexibility for changes to the list and quicker updates. There were four comments to the proposal, all of which supported it. The final rule adopts the proposal without change.

One commenter asked for clarification regarding whether there is a ''grace'' period when an organization is removed from the list and what the timeline would be for a SAP to be 're-qualified' under one of the approved organizations. When a certifying organization is added or removed from the list, the Department intends to notify the list-serve subscribers of the change. Since all SAPs will be required to subscribe to the list-serve, each SAP would receive this important notification. However, specific details regarding ''grace periods for requalification'' would depend upon the facts of each situation and would, therefore, be guidance that ODAPC would provide at the relevant times.

J. Prohibition From Using the DOT or DOT Agency Name, Logos, or Other Official Branding

The Department is concerned that some service agents misrepresented themselves as approved, certified, or endorsed by the Department, by means including, but not limited to, the use of a DOT or DOT agency logo, title, or emblem. Where we have found these misuses of DOT or DOT agency names, logos, or other official branding, ODAPC has taken action under the Public Interest Exclusion provisions to issue Notices of Corrective Actions.

The Department does not approve, certify, or endorse service agents or their activities. We regard the use of such symbols or other means as implying approval, certification or endorsement. When a service agent makes such a representation, the Department views it as false and deceptive holding-out by a party not part of the Federal Government. For this reason, the NPRM proposed to specifically add such false representations to the grounds on which the Department could initiate a PIE proceeding against the offender.

Five of the six comments on this subject supported this proposal and its rationale. The sixth disagreed, on the basis that DOT did not articulate a safety basis for the proposal and that it could impose an unnecessary burden on companies using agency ''brands'' to distinguish tests.

The basis for the proposal is to prevent false and deceptive representations by organizations marketing to DOT employers. Such misrepresentations are at least misleading and at worst deliberately deceptive. When a private party misrepresents that it is part of or that it is certified, approved or endorsed by the DOT or a DOT agency, this can have safety implications for an employer that relies on the holding out of an endorsement if the service agent does not provide services in accordance with DOT requirements. The Department and the DOT Agencies are not ''brands,'' and their names should not be used as if they were.

One of the commenters who supported the proposal noted that training materials should be able to include materials that may contain screen shots or references to DOT Web sites, and publications that contain DOT logos, titles, etc. We agree. We appreciate that employers and service agents reproduce our publications and other materials containing the DOT logos and this regulatory change would not prohibit members of the public from using and/or reproducing the materials that are produced by ODAPC and/or the DOT Agencies. The non-deceptive use of such training materials is not something that we would view as violating our rules because it does not indicate approval or certification by the Department or a DOT agency.

K. Removing Obsolete Compliance Dates

The NPRM proposed removing obsolete compliance dates from several sections. For example, former § 40.33(d) established compliance dates for training then-existing collectors in 2001–2003. Similar training deadlines, all of which were established as part of the transition to the 1999 revision of Part 40 from previous editions, were found in §§ 40.121 (MROs), 40.213 (BATs/STTs), and 40.281 (SAPs). In addition, §§ 40.45 and 40.203 contained a 2011 date to complete a transition to a revised custody and control form. There were four comments on these changes, all of which supported them. These proposed changes are adopted in the final rule. In § 40.121(d), we also eliminated, as a commenter suggested, a reference to continuing education units tied to one of the obsolete compliance dates.

L. Editorial Corrections

In drafting the NPRM, we noted a few sections in which editorial corrections would be helpful for purposes of clarification. In § 40.67(n), we changed ''collector'' to ''service agent'' to clarify that all service agents had a responsibility to ensure that a directly observed collection was conducted when necessary. In § 40.162(c) a reference to § 40.159(f) was corrected to cite paragraph (g) of that section. In § 40.233(b)(4), a reference to § 40.333(a)(2) was corrected to cite paragraph (a)(3) of that section. There were three comments on these proposals, all of which agreed with the proposed changes. These changes are adopted in the final rule.

M. Updating Specified Appendices to Part 40

The NPRM proposed to update the following appendices: Appendices B and C, to add the four semi-synthetic opioids to the drugs listed and remove MDEA; Appendix D, to update a web link; and Appendix H, to remove the instruction sheet for the Management Information System Data Collection from our regulations and move it to our guidance material located on our Web site. The reason for proposing to move the MIS instruction sheet to the ODAPC Web site was to provide greater flexibility for changes and/or updates to this document. There were seven comments to the proposal to update the appendices, all of which supported it. The final rule adopts this proposal without change.

N. Updating Web Links

The Department proposed to update web links in the rule text that have changed on our DOT Web site. There were four comments to this proposal, all of which supported the proposal. In several sections, the Department updated the ODAPC Web address to the

current *http://www.transaportation.gov/odapc.* The affected sections are §§ 40.33, 40.45, 40.105, 40.121, 40.205, 40.213, 40.225, 40.281, and 40.401. In addition, in Appendix D, the Department updated the Web link for reporting split specimens failing to reconfirm to *https://www.transportation.gov/content/split-specimen-cancellation-notification-49-cfr-part-40187-appendix-d.* These updates are adopted in the final rule.

O. Alcohol Testing Device Web Links

Though not among the originally proposed changes, we are making a technical amendment to make it easier to permit employers to use alcohol testing devices approved by the National Highway Traffic Safety Administration (NHTSA), which are the only devices permitted to be used for DOT alcohol testing. Since 1994, the regulation has required employers and service agents to only us a device once the device was approved by NHTSA and appeared on NHTSA's conforming products lists (CPLs) for alcohol screening devices (ASDs) and Evidential Breath Testing Devices (EBTs). NHTSA used the CPLs to add approved devices and remove devices as appropriate. Because there was no regular schedule with which the CPLs were published, employers and alcohol technicians were prohibited by the regulation from using newly approved devices because a new CPL was not published. To permit employers and alcohol technician the ability to use a device as soon possible after NHTSA approves it, we will now list the NHTSA-approved ASDs on a new ODAPC Web page entitled ''Approved Screening Devices to Measure Alcohol in Bodily Fluids'' and we will now list the NHTSA approved EBTs on new ODAPC Web page for ''Approved Evidential Breath Measurement Devices.'' Although, we will no longer require regulated parties to check the actual CPL, we will continue to rely on NHTSA for approval and removal of the devices. ODAPC will take responsibility for creating and continuing to keep the Web pages updated whenever NHTSA notifies us that a device has been approved and added to the list, or removed from the list. This is purely an administrative change as to where to find the list of approved devices. There are no costs associated with this technical change and it should be burden-reducing because it will avoid confusion that has been occurring for DOT-regulated parties and for the product manufacturers. Accordingly, we have made changes to §§ 40.3; 40.229; 40.231; 40.233 and 40.235.

VI. Other Comments

There were two comments concerning the cost-benefit analysis. Those comments are addressed in the regulatory analysis section titled Executive Order 12866 and 13563 and DOT's Regulatory Policies and Procedures.

There were a number of comments that were outside the scope of the NPRM, such as including (or not including) hair or oral fluid testing in the DOT program, reducing the subject matter of refresher training for BATs/STTs, including additional drugs (*e.g.,* benzodiasepines) in the drug testing panel, providing more oversight of MRO decisions, changing some criteria for testing in the Federal Transit Administration rules (49 CFR part 655), broadening the use of electronic signatures in the program, allowing laboratories to use their own protocols for substituted specimen situations, reporting from laboratories to MROs through a third party, and criteria for determining when a test is considered to have been refused. While these and other matters may be worth consideration at a later time, they are outside the scope of the present rulemaking.

VII. Regulatory Analyses and Notices

Changes to Federal regulations are subject to a number of regulatory requirements, which are identified and discussed below. First, Executive Orders 12866 and 13563 direct that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96–354), as codified in 5 U.S.C. 601 *et seq.,* requires agencies to analyze the economic impact of regulatory changes on small entities. The Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*) requires that DOT consider the impact of paperwork and other information collection burdens imposed on the public and, under the provisions of PRA section 3507(d), obtain approval from OMB for each collection of information it conducts, sponsors, or requires through regulations. Section (a)(5) of division H of the Fiscal Year 2005 Omnibus Appropriations Act, Public Law 108–447, 118 Stat. 3268 (Dec. 8, 2004) and section 208 of the E-Government Act of 2002, Public Law 107–347, 116 Stat. 2889 (Dec. 17, 2002) requires DOT to conduct a Privacy Impact Assessment (PIA) of a regulation that will affect the privacy of individuals. Finally, the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) requires DOT to analyze this action to determine whether it will have an effect on the quality of the environment. This portion of the preamble summarizes the DOT's analyses of these impacts with respect to this rule.

Executive Order 12866 and 13563 and DOT's Regulatory Policies and Procedures

This final rule is not a significant regulatory action under Executive Order 12866 and 13563, as well as the Department's Regulatory Policies and Procedures (44 FR 11034). It proposes to harmonize specific Part 40 procedures with recently mandated HHS Guidelines and, in the interest of improving efficiency, make certain program modifications. As such, this proposal would not impose any major policy changes and would not impose any significant new costs or burdens.

Costs

The NPRM

As noted in the Department's NPRM, the HHS Mandatory Guidelines addressed the burdens associated with the addition of new drugs to the drug-testing panel (82 FR 7920, January 23, 2017). The cost impact of drug testing for oxycodone, oxymorphone, hydrocodone, and hydromorphone would be minimal because HHS determined that all HHS-certified laboratories testing specimens from Federal agencies are currently conducting tests for one or more of these analytes on non-regulated urine specimens. HHS further indicated in its analysis that laboratory personnel currently are trained to test for the additional drugs and test methods already have been implemented. Many HHS-certified laboratories conduct non-regulated tests for transportation employers who already include the four semi-synthetic opioids in their non-regulated testing programs. For those employers, therefore, shifting the four drugs from non-regulated tests to regulated tests would not increase testing costs.

HHS determined that the costs associated with implementation of testing for the four additional semi-synthetic opioids would be approximately $0.11–$0.30 per test. Once the testing has been implemented, the cost per specimen for initial testing for the added analytes would range from $.06 to $0.20 due to reagent costs. Current costs for each confirmatory test range from $5.00 to $10.00 for each specimen reported as positive due to

costs of sample preparation and analysis. HHS indicated that based on information from non-regulated workplace drug testing for these analytes in 2012 and testing performed on de-identified federally regulated specimens in 2011, approximately 1% of the submitted specimens is expected to be confirmed as positive for the added analytes. Therefore, HHS indicates that the added cost for confirmatory testing will be $0.05 to $0.10 per submitted specimen.

Approximately 6.3 million DOT-regulated tests occur per year. DOT considered the maximum ranges HHS provided in its analysis. Therefore, with the projected maximum implementation cost per specimen of $0.30, the maximum cost per specimen of initial testing at $0.20, and the maximum cost per specimen of confirmation testing at $0.10, the additional cost per urine test would be an additional $0.60. Under the new HHS Mandatory Guidelines, and based on an estimated 6.3 million DOT tests conducted annually, a cost of approximately $3,800,000 would be realized by employers subject to DOT-regulated testing ($0.60 × 6,300,000 DOT tests annually = $3,780,000).

HHS indicated that there will be minimal costs associated with adding MDA as an initial test analyte because the current immunoassays can be adapted to test for this analyte. According to HHS, before a lab is allowed to test regulated specimens for MDA, HHS must test three groups of performance test, or ''PT'' samples. HHS provides the PT samples at no cost to its certified laboratories but HHS estimates that the laboratory costs to conduct the PT testing would range from $900 to $1,800 for each certified laboratory. There are approximately 27 HHS-certified laboratories who process DOT drug tests. With the maximum cost estimate of $1,800 for each certified laboratory, a cost of approximately $48,600 would be realized for DOT ($1,800 × 27 laboratories = $48,600.)

Testing for additional drugs would result in new MRO costs, as MROs would have additional review and verification to conduct. Based on the positivity rates from non-regulated workplace drug testing and the additional review of specimens with a laboratory confirmed positive for prescription medications, HHS estimates that MRO costs would increase by approximately 3%. The additional costs for testing and MRO review would be incorporated into the overall cost for the Federal agency submitting the specimen to the laboratory. HHS bases the estimation of costs incurred on overall cost to the Federal agency affected because cost is usually based on all specimens submitted from an agency, rather than individual specimen testing costs or MRO review of positive specimens. Based on this analysis, therefore, DOT projects an additional MRO cost of $189,000 (.03 projected increase × 6,300,000 DOT tests annually).

Comments

There were two comments on our cost estimates. One questioned the projected cost savings of the proposal to eliminate the blind specimen testing requirement. Specifically, the commenter said that the cost savings were inflated because we did not take into consideration the 50-blind specimen limit per quarter and that blinds are not required to be submitted for employers with fewer than 2,000 employees. The same commenter also questioned why DOT did not factor in increased potential costs that were mentioned by commenters in the HHS rulemaking such as, increased estimated MRO costs of 10% and start-up costs to laboratories to implement testing for the additional analytes. Another commenter requested that we further explain the analysis for the costs associated with confirmation testing. Specifically, the commenter wanted us to adjust the cost-benefit analysis to address confirmation test costs for the four prescription drug initial positive tests, not just the projected 1% of the specimens that are confirmed positive. The commenter suggested that, when making this calculation, DOT consider using laboratory data for the percentage of positive test results that will require a confirmation test.

DOT Response

Regarding the blind specimen costs, our response is included in the 'cost-savings' paragraph of this section. As for the comment about not factoring in potential costs that were mentioned by commenters in the HHS rulemaking, we did not see the need to address them since HHS already responded to those comments (82 FR 7931). In short, HHS assumed the start-up costs for testing the four semi-synthetic opioids, and changes to the amphetamines would be de minimis given that laboratories could use existing immunoassays.

To further explain the costs associated with verifying test results for the additional semi-synthetic opioids, we agree with the commenters that the 3% estimated by HHS may not be sufficient for calculating the costs to the DOT-regulated industries. We have added the full cost of the MRO review of the non-negative results for the four semi-synthetic opioids instead of just the additional 3% estimated by HHS. As we understand it, the upper limit cost of a MRO review for non-negatives is approximately $60. Given the estimated 1% (63,000) of specimens confirming for the semi-synthetic opioids, the estimated additional costs for MRO reviews resulting from this final rule would be $3,780,000 ($60 × 63,000).

Regarding the specific comment for DOT to consider the confirmation test costs for the four prescription drug initial positive tests, not just the projected 1% of the specimens that are confirmed positive, the Department has no basis to conclude that there will be an additional cost to DOT-regulated employers for specimens that screen positive but do not confirm as positive. Furthermore, the commenters did not provide any data to support their assertion. As we understand it and as explained in our ''What Employers Need to Know About DOT Drug and Alcohol Testing'' handbook, employers may choose one of two pricing structures, bundled and unbundled. Bundled pricing means that one-price-fits-all. The price of the bundle is dependent on various factors like volume and positive rate. In unbundled pricing, it is 'a la carte' pricing for each test the laboratory has to run. Our projected costs assume a bundled pricing structure since it appears to be widely used.

We also want to address two issues related to information we provided in our NPRM. First, we incorrectly associated the full cost of the Proficiency Testing (PT) to only the cost of testing for MDA. However, based on HHS final rule [82 FR 7931], the cost for PT testing ($48,600) is for all the semi-synthetic opioids and MDA, not just MDA. Accordingly, our cost analysis now correctly articulates that the cost of PT is for all the compounds as outlined in HHS' final rule. This does not change the quantified cost of the rule. Second, we estimated that the per specimen cost would be an additional $0.60 (implementation cost of $0.30 and a maximum screening and confirmation testing cost of $0.30) for a total cost of $3,780,000 ($0.60 × 6,300,000). As we mentioned earlier, HHS assumed the start-up costs would be de minimis. DOT agrees that the start-up costs are expected to be de minimis. Therefore, we have removed the implementation costs (approximately an additional $0.30 per specimen) that were originally proposed. Thus, a cost of $1,890,000 ($0.30 × 6,300,000) would be realized by employers subject to DOT-regulated testing and not the $3,780,000 we originally estimated.

On a final note, we acknowledge potential costs that were not discussed in the NPRM for those employees with positive test results that would potentially go through the return-to-duty process. As we mentioned earlier, we estimated that 1% (63,000) of the specimens will be confirmed for one or more of the semi-synthetic opioids. Based on MRO's experiences in non-DOT testing that 80% of the semi-synthetic results will be downgraded to 'negative' due to legitimate medical explanations (*e.g.,* valid prescriptions), we estimate that only 12,600 of the 63,000 laboratory confirmed positives will be reported by the MRO as verified positive. We further estimate that, of the 12,600 verified positive results, approximately 25% (3,150) will participate in the return-to-duty process. The other individuals will not return to positions that require DOT testing or will continue working at their non-DOT positions. With the mandatory Substance Abuse Professional (SAP) evaluation costing approximately $400, the return-to-duty test costing approximately $50, and the minimum of six follow-up tests costing approximately $300 (6 × $50), the return-to-duty cost would be approximately $750 per employee. Altogether, the Department estimates the total return-to-duty costs to be approximately $2,362,500 (3,150 × $750).

This estimate does not include costs associated with education or treatment that the employee completes before taking the required return-to-duty test. A verified positive result merely identifies that the individual needs to seek treatment. The positive result does not create the employee's condition. By seeking treatment sooner than later, the potential costs associated with education and treatment for an individual that tests positive could be less than if the employee did not test positive.

Cost-Savings

The NPRM

In the NPRM, DOT estimated a cost-savings of at least $3.1 million per year from the elimination of the requirement for employers to submit blind specimen testing to laboratories (estimated at approximately $50 per test). This estimate of cost-savings is based on the regulatory analysis performed when DOT reduced blind specimen testing in 2000 (65 FR 79462, 79517, Dec. 19, 2000), adjusted for inflation. Based on the blind specimen requirements made effective in 2000 for employers to submit 1% of 6,300,000 DOT tests for blind testing conducted annually at a cost of approximately $50 per test yields a cost-savings of $3,150,000 (63,000 × $50).

Comments

One commenter suggested that the savings from the elimination of blind specimen testing had been overestimated, because the cost-benefit analysis did not take into account the 50-specimen maximum and the requirement that only employers with more than 2,000 covered employees were required to submit blind specimens.

DOT Response

We revised our calculation to take into consideration the commenter's concerns. Our revised calculation takes into account: The estimated number of DOT-regulated employers (728,324) and employees (5,192,065); the known number of employers (175) with employee counts from 2,000 to 50,000; an estimated number of C/TPAs (2,158) with an employee count of 2,000; the 25% random testing rate and estimated number of other tests; the 1% blind specimen rate; and an estimated cost of $50 per blind specimen test. The estimated number of C/TPAs is based on the assumption that the smaller employers (employers with less than 2,000 employees), would join a C/TPA to administer their random testing pools and other aspects of the DOT program and include them in their consortium. Accordingly, we project annual cost-savings from eliminating the blinds would be $1,298,016. We have placed in the docket for this rulemaking a document describing the basis for this estimate and calculation in greater detail.

Net Economic Impact

The DOT believes the projected cost to the DOT of implementing testing for the additional drugs being added to the drug-testing regimen will be minimal. The projected $1,938,600 for the four semi-synthetic opioid drugs and PT testing ($1,890,000 and $48,600 respectively) and the $3,780,000 projected MRO costs would result in total projected costs of $5,718,600. The projected cost savings from eliminating the blind specimen testing requirement would be $1,298,016. The estimated net cost impact of this proposal, therefore, would be $4,420,584 ($5,718,600 − $1,298,016) per year. This rule will not have an economically significant impact under Executive Order 12866 because it would not have an annual effect on the economy of $100 million or more, nor do we have any basis to conclude that it would adversely affect any sector of the economy.

Regulatory Flexibility Analysis

The Regulatory Flexibility Act of 1980 (Pub. L. 96–354, ''RFA''), 5 U.S.C. 601 *et seq.,* establishes ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration.'' The RFA covers a wide-range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a proposed rule would have a significant economic impact on a substantial number of small entities. If the agency determines that it would, the agency must prepare a regulatory flexibility analysis. However, if an agency determines that it is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) provides that the head of the agency may so certify, and a regulatory flexibility analysis would not be required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

This final rule conforms the existing DOT drug-testing panel to recently issued HHS Mandatory Guidelines and, with certain minor amendments (mostly editorial), to improve the efficiency of the DOT drug-testing program. The net costs of this rule do not constitute a significant burden to any entity, small or otherwise. Consequently, the DOT certifies, under the RFA, that this rule will not have a significant economic impact on a substantial number of small entities.

Federalism

This rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13132 (''Federalism''). This rule does not include requirements that (1) have substantial direct effects on the States, the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government, (2) impose substantial direct compliance costs on State and local governments, or (3)

preempt State law. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

Paperwork Reduction Act/Privacy Act

The Paperwork Reduction Act requires that the DOT consider the impact of paperwork and other information collection burdens imposed on the public. Information collections for Part 40 currently are approved under OMB Control No. 2105–0529. The Privacy Act provides safeguards against invasion of personal privacy through the misuse of records by Federal Agencies. It establishes controls over what personal information is collected, maintained, used and disseminated by agencies in the executive branch of the Federal government.

This rule does not create any new paperwork or other information collection burdens needing approval, nor would it require any further protections under the Privacy Act.

National Environmental Policy Act

The Department has analyzed the environmental impacts of this action pursuant to the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) and has determined that it is categorically excluded pursuant to DOT Order 5610.1C, Procedures for Considering Environmental Impacts (44 FR 56420, Oct. 1, 1979). Categorical exclusions are actions identified in an agency's NEPA implementing procedures that do not normally have a significant impact on the environment and therefore do not require either an environmental assessment (EA) or environmental impact statement (EIS). See 40 CFR 1508.4. In analyzing the applicability of a categorical exclusion, Federal agencies also must consider whether extraordinary circumstances are present that would warrant the preparation of an EA or EIS. This rule does not meet any of these criteria. The Department does not anticipate any environmental impacts, and there are no extraordinary circumstances present in connection with this rulemaking.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) does not require a written statement for this final rule because the rule does not include a Federal mandate that may result in the expenditure in any one year of $155,000,000 or more by State, local, and tribal governments, or the private sector.

Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771 titled ''Reducing Regulation and Controlling Regulatory Costs,'' directs that, unless prohibited by law, whenever an executive department or agency publicly proposes for notice and comment or otherwise promulgates a new regulation, it shall identify at least two existing regulations to be repealed. In addition, any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs. This rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

List of Subjects in 49 CFR Part 40

Administrative practice and procedures, Alcohol abuse, Alcohol testing, Drug abuse, Drug testing, Laboratories, Reporting and recordkeeping requirements, Safety, Transportation.

The Final Rule

For reasons discussed in the preamble, the Department of Transportation is amending part 40 of Title 49 Code of Federal Regulations, as follows:

PART 40—PROCEDURES FOR TRANSPORTATION WORKPLACE DRUG AND ALCOHOL TESTING PROGRAMS

■ 1. The authority citation for 49 CFR part 40 is revised to read as follows:

Authority: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 54101 *et seq.*

■ 2. Amend § 40.3 as follows:
■ a. Revise the definition of ''*Alcohol screening device (ASD)*'';
■ b. Remove the definition ''*Blind specimen or blind performance test specimen*'';
■ c. Revise and reorder (in correct alphabetical order) the definition ''*DOT, the Department, DOT Agency*'';
■ d. Revise the definition ''*Drugs*''; and
■ e. Revise the definition of ''*Evidential breath testing device (EBT)*''.

The revisions read as follows:

§ 40.3 What do the terms used in this part mean?

* * * * *

Alcohol screening device (ASD). A breath or saliva device, other than an EBT, that is approved by the National Highway Traffic Safety Administration (NHTSA) and appears on ODAPC's Web page for ''Approved Screening Devices to Measure Alcohol in Bodily Fluids'' because it conforms to the model specifications from NHTSA.

* * * * *

DOT, The Department, DOT Agency. These terms encompass all DOT agencies, including, but not limited to, the Federal Aviation Administration (FAA), the Federal Railroad Administration (FRA), the Federal Motor Carrier Safety Administration (FMCSA), the Federal Transit Administration (FTA), the National Highway Traffic Safety Administration (NHTSA), the Pipeline and Hazardous Materials Safety Administration (PHMSA), and the Office of the Secretary (OST). For purposes of this part, the United States Coast Guard (USCG), in the Department of Homeland Security, is considered to be a DOT agency for drug testing purposes only since the USCG regulation does not incorporate Part 40 for its alcohol testing program. These terms include any designee of a DOT agency.

* * * * *

Drugs. The drugs for which tests are required under this part and DOT agency regulations are marijuana, cocaine, amphetamines, phencyclidine (PCP), and opioids.

* * * * *

Evidential Breath Testing Device (EBT). A device that is approved by the National Highway Traffic Safety Administration (NHTSA) for the evidential testing of breath at the .02 and .04 alcohol concentrations, and appears on ODAPC's Web page for ''Approved Evidential Breath Measurement Devices'' because it conforms with the model specifications available from NHTSA.

* * * * *

■ 3. Revise § 40.26 to read as follows:

§ 40.26 What form must an employer use to report Management Information System data to a DOT agency?

As an employer, when you are required to report MIS data to a DOT agency, you must use the U.S. Department of Transportation Drug and Alcohol Testing MIS Data Collection Form to report that data. You must use the form at appendix H to this part. You may view and download the instructions on the Department's Web site (*https://www.transportation.gov/odapc*). You must submit the MIS report in accordance with rule requirements (*e.g.,* dates for submission, selection of companies required to submit, and method of reporting) established by the DOT agency regulating your operation.

§ 40.29 [Amended]

■ 4. Amend § 40.29 by removing the entry ''§§ 40.103–40.105—Blind specimen requirements.''

■ 5. Amend § 40.33 by revising paragraphs (a) and (d) to read as follows:

§ 40.33 What training requirements must a collector meet?

* * * * *

(a) *Basic information.* You must be knowledgeable about this part, the current ''DOT Urine Specimen Collection Procedures Guidelines,'' and DOT agency regulations applicable to the employers for whom you perform collections. DOT agency regulations, the DOT Urine Specimen Collection Procedures Guidelines, and other materials are available from ODAPC (Department of Transportation, 1200 New Jersey Avenue SE., Washington DC, 20590, 202–366–3784, or on the ODAPC Web site (*https://www.transportation.gov/odapc*). You must keep current on any changes to these materials. You must subscribe to the ODAPC list-serve at: *https://www.transportation.gov/odapc/get-odapc-email-updates.*

* * * * *

(d) You must meet the requirements of paragraphs (b) and (c) of this section before you begin to perform collector functions.

* * * * *

§ 40.37 [Amended]

■ 6. Amend § 40.37 by removing the entry ''§ 40.103—Processing blind specimens.''

§ 40.45 [Amended]

■ 7. Amend § 40.45(a) by removing the parenthetical ''(*http://www.dot.gov/odapc*)'' and adding, in its place ''(*http://www.transportation.gov/odapc*)'' and § 40.45(b) by removing the parenthetical ''(*e.g.,* that after November 30, 2011, they must not use an expired CCF for DOT urine collections)''

■ 8. Amend § 40.67 by revising paragraph (n) to read as follows:

§ 40.67 When and how is a directly observed collection conducted?

* * * * *

(n) As a service agent, when you learn that a directly observed collection should have been collected but was not, you must inform the employer that it must direct the employee to have an immediate recollection under direct observation.

■ 9. Amend § 40.83 by revising paragraph (c) to read as follows:

§ 40.83 How do laboratories process incoming specimens?

* * * * *

(c) You must inspect each specimen and CCF for the following ''fatal flaws:''

(1) There is no CCF;

(2) In cases where a specimen has been collected, there is no specimen submitted with the CCF;

(3) There is no printed collector's name and no collector's signature;

(4) Two separate collections are performed using one CCF;

(5) The specimen ID numbers on the specimen bottle and the CCF do not match;

(6) The specimen bottle seal is broken or shows evidence of tampering, unless a split specimen can be redesignated (see paragraph (h) of this section);

(7) There is an insufficient amount of urine in the primary bottle for analysis, unless the specimens can be redesignated (see paragraph (h) of this section).

* * * * *

■ 10. Revise § 40.85 to read as follows:

§ 40.85 What drugs do laboratories test for?

As a laboratory, you must test for the following five drugs or classes of drugs in a DOT drug test. You must not test ''DOT specimens'' for any other drugs.

(a) Marijuana metabolites.

(b) Cocaine metabolites.

(c) Amphetamines.

(d) Opioids.

(e) Phencyclidine (PCP).

■ 11. Amend § 40.87 by revising paragraph (a) to read as follows:

§ 40.87 What are the cutoff concentrations for drug tests?

(a) As a laboratory, you must use the cutoff concentrations displayed in the following table for initial and confirmatory drug tests. All cutoff concentrations are expressed in nanograms per milliliter (ng/mL). The table follows:

Initial test analyte	Initial test cutoff [1]	Confirmatory test analyte	Confirmatory test cutoff concentration
Marijuana metabolites (THCA) [2]	50 ng/mL [3]	THCA	15 ng/mL.
Cocaine metabolite (Benzoylecgonine)	150 ng/mL [3]	Benzoylecgonine	100 ng/mL.
Codeine/ Morphine	2000 ng/mL	Codeine	2000 ng/mL.
		Morphine	2000 ng/mL.
Hydrocodone/ Hydromorphone	300 ng/mL	Hydrocodone	100 ng/mL.
		Hydromorphone	100 ng/mL.
Oxycodone/ Oxymorphone	100 ng/mL	Oxycodone	100 ng/mL.
		Oxymorphone	100 ng/mL.
6-Acetylmorphine	10 ng/mL	6-Acetylmorphine	10 ng/mL.
Phencyclidine	25 ng/mL	Phencyclidine	25 ng/mL.
Amphetamine/ Methamphetamine	500 ng/mL	Amphetamine	250 ng/mL.
		Methamphetamine	250 ng/mL.
MDMA [4]/MDA [5]	500 ng/mL	MDMA	250 ng/mL.
		MDA	250 ng/mL.

[1] For grouped analytes (i.e., two or more analytes that are in the same drug class and have the same initial test cutoff):

Immunoassay: The test must be calibrated with one analyte from the group identified as the target analyte. The cross-reactivity of the immunoassay to the other analyte(s) within the group must be 80 percent or greater; if not, separate immunoassays must be used for the analytes within the group.

Alternate technology: Either one analyte or all analytes from the group must be used for calibration, depending on the technology. At least one analyte within the group must have a concentration equal to or greater than the initial test cutoff or, alternatively, the sum of the analytes present (i.e., equal to or greater than the laboratory's validated limit of quantification) must be equal to or greater than the initial test cutoff.

[2] An immunoassay must be calibrated with the target analyte, Δ-9-tetrahydrocannabinol-9-carboxylic acid (THCA).

[3] *Alternate technology (THCA and Benzoylecgonine):* When using an alternate technology initial test for the specific target analytes of THCA and Benzoylecgonine, the laboratory must use the same cutoff for the initial and confirmatory tests (i.e., 15 ng/mL for THCA and 100ng/mL for Benzoylecgonine).

[4] Methylenedioxymethamphetamine (MDMA).

[5] Methylenedioxyamphetamine (MDA).

* * * * *

§ 40.103 [Removed]

■ 12. Remove § 40.103.

§ 40.105 [Removed]

■ 13. Remove § 40.105.

■ 14. Amend § 40.121 by revising paragraphs (b)(3) and (c)(3), and the paragraph (d) introductory text to read as follows:

§ 40.121 Who is qualified to act as an MRO?

* * * * *

(b) * * *

(3) You must be knowledgeable about this part, the DOT MRO Guidelines, and the DOT agency regulations applicable to the employers for whom you evaluate drug test results, and you must keep current on any changes to these materials. You must subscribe to the ODAPC list-serve at *https://www.transportation.gov/odapc/get-odapc-email-updates.* DOT agency regulations, DOT MRO Guidelines, and other materials are available from ODAPC (Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, 202–366–3784), or on the ODAPC Web site (*http://www.transportation.gov/odapc*).

(c) * * *

(3) You must meet the requirements of paragraphs (a), (b), and (c) of this section before you begin to perform MRO functions.

(d) *Requalification training.* During each five-year period from the date on which you satisfactorily completed the examination under paragraph (c)(2) of this section, you must complete requalification training.

* * * * *

■ 15. Amend § 40.123 by revising paragraph (e) to read as follows:

§ 40.123 What are the MRO's responsibilities in the DOT drug testing program?

* * * * *

(e) You must act to investigate and correct problems where possible and notify appropriate parties (*e.g.,* HHS, DOT, employers, service agents) where assistance is needed, (*e.g.,* cancelled or problematic tests, incorrect results).

* * * * *

■ 16. Amend § 40.135 by revising paragraph (e) to read as follows:

§ 40.135 What does the MRO tell the employee at the beginning of the verification interview?

* * * * *

(e) You 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 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.

■ 17. Amend § 40.137 by revising the section heading and paragraph (a) to read as follows:

§ 40.137 On what basis does the MRO verify test results involving marijuana, cocaine, amphetamines, semi-synthetic opioids, or PCP?

(a) As the MRO, you must verify a confirmed positive test result for marijuana, cocaine, amphetamines, semi-synthetic opioids (*i.e.,* hydrocodone, hydromorphone, oxycodone, and oxymorphone), and/or PCP unless the employee presents a legitimate medical explanation for the presence of the drug(s)/metabolite(s) in his or her system. In determining whether an employee's legally valid prescription consistent with the Controlled Substances Act for a substance in these categories constitutes a legitimate medical explanation, you must not question whether the prescribing physician should have prescribed the substance.

* * * * *

■ 18. Amend § 40.139 by revising the section heading and paragraphs (c) introductory text and (c)(3) to read as follows:

§ 40.139 On what basis does the MRO verify test results involving 6-acetylmorphine, codeine, and morphine?

* * * * *

(c) For all other codeine and morphine positive results, you must verify a confirmed positive test result only if you determine that there is clinical evidence, in addition to the urine test, of unauthorized use of any opium, opiate, or opium derivative (*i.e.,* morphine, codeine, or heroin).

* * * * *

(3) To be the basis of a verified positive result for codeine or morphine, the clinical evidence you find must concern a drug that the laboratory found in the specimen. (For example, if the test confirmed the presence of codeine, and the employee admits to unauthorized use of hydrocodone, you must not verify the test positive for codeine. The admission must be for the substance that was found through the actual drug test.)

* * * * *

■ 19. Amend § 40.141 by revising paragraph (b) to read as follows:

§ 40.141 How does the MRO obtain information for the verification decision?

* * * * *

(b) If the employee asserts that the presence of a drug or drug metabolite in his or her specimen results from taking prescription medication (*i.e.,* a legally valid prescription consistent with the Controlled Substances Act), you must review and take all reasonable and necessary steps to verify the authenticity of all medical records the employee provides. You may contact the employee's physician or other relevant medical personnel for further information. You may request an HHS-certified laboratory with validated protocols (see § 40.81(c)) to conduct testing for D,L stereoisomers of amphetamine and methamphetamine or testing for tetrahydrocannabivarin (THC- V) when verifying lab results, as you determine necessary.

■ 20. Amend § 40.162 by revising paragraph (c) to read as follows:

§ 40.162 What must MROs do with multiple verified results for the same testing event?

* * * * *

(c) As an exception to paragraphs (a) and (b) of this section, as the MRO, you must follow procedures at § 40.159(g) when any verified non-negative result is also invalid.

§ 40.169 [Amended]

■ 21. Amend § 40.169 by removing the entry ''§ 40.105—Notification of discrepancies in blind specimen results.''

§ 40.189 [Amended]

■ 22. Amend § 40.189 by removing the entry ''§ 40.103—Blind split specimens.''

■ 23. Amend § 40.193 by revising paragraph (b)(4) to read as follows:

§ 40.193 What happens when an employee does not provide a sufficient amount of urine for a drug test?

* * * * *

(b) * * *

(4) If the employee has not provided a sufficient specimen within three hours of the first unsuccessful attempt to provide the specimen, you must discontinue the collection, note the fact on the ''Remarks'' line of the CCF (Step 2), and immediately notify the DER. You must also discard any specimen the employee previously provided to include any specimen that is ''out of temperature range'' or shows signs of tampering. In the remarks section of the CCF that you will distribute to the MRO and DER, note the fact that the employee provided an ''out of temperature range specimen'' or ''specimen that shows signs of tampering'' and that it was discarded because the employee did not provide a second sufficient specimen.

* * * * *

■ 24. Amend § 40.199 by revising paragraph (b) to read as follows:

§ 40.199 What problems always cause a drug test to be cancelled?

* * * * *

(b) The following are ''fatal flaws'':

(1) There is no CCF;

(2) In cases where a specimen has been collected, there is no specimen submitted with the CCF;

(3) There is no printed collector's name and no collector's signature;

(4) Two separate collections are performed using one CCF;

(5) The specimen ID numbers on the specimen bottle and the CCF do not match;

(6) The specimen bottle seal is broken or shows evidence of tampering (and a split specimen cannot be re-designated, see § 40.83(h)); or

(7) Because of leakage or other causes, there is an insufficient amount of urine in the primary specimen bottle for analysis and the specimens cannot be re-designated (see § 40.83(h)).

* * * * *

■ 25. Amend § 40.203 by revising paragraph (d)(3) to read as follows:

§ 40.203 What problems cause a drug test to be cancelled unless they are corrected?

* * * * *

(d) * * *

(3) The collector uses a non-Federal form or an expired CCF for the test. This flaw may be corrected through the procedure set forth in § 40.205(b)(2), provided that the collection testing process has been conducted in accordance with the procedures in this part in an HHS-certified laboratory.

■ 26. Add § 40.210 to subpart I to read as follows:

§ 40.210 Are drug tests other than urine permitted under the regulations?

No. Drug tests other than on urine specimens are not authorized for testing under this part. Only urine specimens screened and confirmed at HHS certified laboratories (see § 40.81) are allowed for drug testing under this part. Point-of-collection urine testing or instant tests are not authorized.

■ 27. Amend § 40.213 by revising paragraphs (a), (d), and (e) to read as follows:

§ 40.213 What training requirements must STTs and BATs meet?

* * * * *

(a) You must be knowledgeable about the alcohol testing procedures in this part and the current DOT guidance. Procedures and guidance are available from ODAPC (Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590, 202–366–3784, or on the ODAPC Web site, *http://www.transportation.gov/odapc*). You must keep current on any changes to these materials. You must subscribe to the ODAPC list-serve at (*https://www.transportation.gov/odapc/get-odapc-email-updates*).

* * * * *

(d) You must meet the requirements of paragraphs (b) and (c) of this section before you begin to perform STT or BAT functions.

(e) *Refresher training.* No less frequently than every five years from the date on which you satisfactorily complete the requirements of paragraphs (b) and (c) of this section, you must complete refresher training that meets all the requirements of paragraphs (b) and (c) of this section.

* * * * *

§ 40.225 [Amended]

■ 28. Amend § 40.225(a) by removing the parenthetical ''(*http://www.dot.gov/dapc*)'' and adding, in its place ''(*http://www.transportation.gov/odapc*)''

■ 29. Revise § 40.229 to read as follows:

§ 40.229 What devices are used to conduct alcohol screening tests?

ASDs listed on ODAPC's Web page for ''Approved Screening Devices to Measure Alcohol in Bodily Fluids'' and EBTs listed on ODAPC's Web page for ''Approved Evidential Breath Measurement Devices'' are the only devices you are allowed to use to conduct alcohol screening tests under this part. You may use an ASD for DOT alcohol tests only if there are instructions for its use in this part. An ASD can be used only for screening tests for alcohol, and must not be used for confirmation tests.

■ 30. Amend § 40.231 by revising paragraph (a) to read as follows:

§ 40.231 What devices are used to conduct alcohol confirmation tests?

(a) EBTs on ODAPC's Web page for ''Approved Evidential Breath Measurement Devices'' that meet the requirements of paragraph (b) of this section are the only devices you may use to conduct alcohol confirmation tests under this part.

* * * * *

■ 31. Amend § 40.233 by revising paragraphs (a) introductory text and (c)(4) to read as follows:

§ 40.233 What are the requirements for proper use and care of EBTs?

(a) As an EBT manufacturer, you must submit, for NHTSA approval, a quality assurance plan (QAP) for your EBT before ODAPC places the EBT on its Web page for ''Approved Evidential Breath Measurement Devices.''

* * * * *

(c) * * *

(4) You must maintain records of the inspection, maintenance, and calibration of EBTs as provided in § 40.333(a)(3).

* * * * *

■ 32. Amend § 40.235 by revising paragraph (a) to read as follows:

§ 40.235 What are the requirements for proper use and care of ASDs?

(a) As an ASD manufacturer, you must submit, for NHTSA approval, a QAP for your ASD before NHTSA approves it and ODAPC places the device on its Web page for ''Approved Screening Devices to Measure Alcohol in Bodily Fluids''. Your QAP must specify the methods used for quality control checks, temperatures at which the ASD must be stored and used, the shelf life of the device, and environmental conditions (*e.g.,* temperature, altitude, humidity) that may affect the ASD's performance.

* * * * *

■ 33. Amend § 40.281 by revising paragraphs (a)(6), (b)(3), and (c)(3) to read as follows:

§ 40.281 Who is qualified to act as a SAP?

* * * * *

(a) * * *

(6) You are a drug and alcohol counselor certified by an organization listed at *https://www.transportation.gov/odapc/sap.*

(b) * * *

(3) You must be knowledgeable about this part, the DOT agency regulations applicable to the employers for whom you evaluate employees, and the DOT

SAP Guidelines. You must keep current on any changes to these materials. You must subscribe to the ODAPC list-serve at *https://www.transportation.gov/odapc/get-odapc-email-updates.* DOT agency regulations, DOT SAP Guidelines, and other materials are available from ODAPC (Department of Transportation, 1200 New Jersey Avenue SE., Washington DC, 20590 (202–366–3784), or on the ODAPC Web site (*http://www.transportation.gov/odapc*).

(c) * * *

(3) You must meet the requirements of paragraphs (a), (b), and (c) of this section before you begin to perform SAP functions.

* * * * *

■ 34. Amend § 40.331 by revising paragraph (f) to read as follows:

§ 40.331 To what additional parties must employers and service agents release information?

* * * * *

(f) Except as otherwise provided in this part, as a laboratory you must not release or provide a specimen or a part of a specimen to a requesting party, without first obtaining written consent from ODAPC. DNA testing and other types of identity testing are not authorized and ODAPC will not give permission for such testing. If a party seeks a court order directing you to release a specimen or part of a specimen contrary to any provision of this part, you must take necessary legal steps to contest the issuance of the order (*e.g.,* seek to quash a subpoena, citing the requirements of § 40.13). This part does not require you to disobey a court order, however.

* * * * *

■ 35. Amend § 40.365 by revising paragraph (b)(10) to read as follows:

§ 40.365 What is the Department's policy concerning starting a PIE proceeding?

* * * * *

(b) * * *

(10) For any service agent, falsely representing that the service agent or its activities is approved or certified by the Department or a DOT agency (such representation includes, but is not limited to, the use of a Department or DOT agency logo, title, or emblem).

* * * * *

§ 40.401 [Amended]

■ 36. Amend § 40.401(a) by removing the parenthetical ''(*http://www.dot.gov/ost/dapc*)'' and adding, in its place ''(*http://www.transportation.gov/odapc*)''

■ 37. Revise Appendix B to Part 40 to read as follows:

Appendix B to Part 40—DOT Drug-Testing Semi-Annual Laboratory Report to Employers

The following items are required on each laboratory report:

Reporting Period: (inclusive dates)
Laboratory Identification: (name and address)
Employer Identification: (name; may include Billing Code or ID code)
C/TPA Identification: (where applicable; name and address)
1. Specimen Results Reported (total number)
By Test Reason
(a) Pre-employment (number)
(b) Post-Accident (number)
(c) Random (number)
(d) Reasonable Suspicion/Cause (number)
(e) Return-to-Duty (number)
(f) Follow-up (number)
(g) Type of Test Not Noted on CCF (number)
2. Specimens Reported
(a) Negative (number)
(b) Negative and Dilute (number)
3. Specimens Reported as Rejected for Testing (total number)
By Reason
(a) Fatal flaw (number)
(b) Uncorrected Flaw (number)
4. Specimens Reported as Positive (total number) By Drug
(a) Marijuana Metabolite (number)
(b) Cocaine Metabolite (number)
(c) Opioids (number)
(1) Codeine (number)
(2) Morphine (number)
(3) 6–AM (number)
(4) Hydrocodone (number)
(5) Hydromorphone (number)
(6) Oxycodone (number)
(7) Oxymorphone (number)
(d) Phencyclidine (number)
(e) Amphetamines (number)
(1) Amphetamine (number)
(2) Methamphetamine (number)
(3) MDMA (number)
(4) MDA (number)
5. Adulterated (number)
6. Substituted (number)
7. Invalid Result (number)

■ 38. Revise Appendix C to Part 40 to read as follows:

Appendix C to Part 40—DOT Drug-Testing Semi-Annual Laboratory Report to DOT

Mail, fax, or email to:
U.S. Department of Transportation, Office of Drug and Alcohol Policy and Compliance, W62–300, 1200 New Jersey Avenue SE., Washington, DC 20590, *Fax:* (202) 366–3897, *Email: ODAPCWebMail@dot.gov.*

The following items are required on each report:

Reporting Period: (inclusive dates)
Laboratory Identification: (name and address)
1. DOT Specimen Results Reported (total number)
2. Negative Results Reported (total number)
Negative (number)
Negative-Dilute (number)
3. Rejected for Testing Results Reported (total number)
By Reason
(a) Fatal flaw (number)
(b) Uncorrected Flaw (number)
4. Positive Results Reported (total number)
By Drug
(a) Marijuana Metabolite (number)
(b) Cocaine Metabolite (number)
(c) Opioids (number)
(1) Codeine (number)
(2) Morphine (number)
(3) 6–AM (number)
(4) Hydrocodone (number)
(5) Hydromorphone (number)
(6) Oxycodone (number)
(7) Oxymorphone (number)
(d) Phencyclidine (number)
(e) Amphetamines (number)
(1) Amphetamine (number)
(2) Methamphetamine (number)
(3) MDMA (number)
(4) MDA (number)
5. Adulterated Results Reported (total number)
By Reason (number)
6. Substituted Results Reported (total number)
7. Invalid Results Reported (total number)
By Reason (number)

■ 39. Revise Appendix D to Part 40 to read as follows:

Appendix D to Part 40—Report Format: Split Specimen Failure To Reconfirm

Mail, fax, or submit electronically to:

U.S. Department of Transportation, Office of Drug and Alcohol Policy and Compliance, W62–300, 1200 New Jersey Avenue SE., Washington, DC 20590, *Fax: (202) 366–3897.* Submit Electronically: *https://www.transportation.gov/content/split-specimen-cancellation-notification-49-cfr-part-40187-appendix-d*

The following items are required on each report:

1. MRO name, address, phone number, and fax number.

2. Collection site name, address, and phone number.

3. Date of collection.

4. Specimen I.D. number.

5. Laboratory accession number.

6. Primary specimen laboratory name, address, and phone number.

7. Date result reported or certified by primary laboratory.

8. Split specimen laboratory name, address, and phone number.

9. Date split specimen result reported or certified by split specimen laboratory.

10. Primary specimen results (*e.g.,* name of drug, adulterant) in the primary specimen.

11. Reason for split specimen failure-to-reconfirm result (*e.g.,* drug or adulterant not present, specimen invalid, split not collected, insufficient volume).

12. Actions taken by the MRO (*e.g.,* notified employer of failure to reconfirm and requirement for recollection).

13. Additional information explaining the reason for cancellation.

14. Name of individual submitting the report (if not the MRO)

■ 40. Amend Appendix H to Part 40 by:
■ a. Revising the introductory text; and
■ b. Removing the instruction sheet entitled: ''U.S. DEPARTMENT OF

TRANSPORTATION DRUG AND ALCOHOL TESTING MIS DATA COLLECTION FORM INSTRUCTION SHEET''.

The revision reads as follows:

Appendix H to Part 40—DOT Drug and Alcohol Testing Management Information System (MIS) Data Collection Form

The following form is the MIS Data Collection form required for use to report calendar year MIS data.

* * * * *

Issued in Washington, DC on November 3, 2017.

Elaine L. Chao,

Secretary of Transportation.

[FR Doc. 2017–24397 Filed 11–9–17; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 121004518–3398–01]

RIN 0648–XF815

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; 2017 Commercial Accountability Measure and Closure for Gulf Gray Triggerfish

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS implements accountability measures for commercial gray triggerfish in the exclusive economic zone (EEZ) of the Gulf of Mexico (Gulf) through this temporary rule. NMFS projects commercial landings for gray triggerfish will reach the commercial annual catch target (ACT)(commercial quota) by November 18, 2017. Therefore, NMFS is closing the commercial sector for gray triggerfish in the Gulf EEZ on November 18, 2017. This closure is necessary to protect the gray triggerfish resource.

DATES: This rule is effective 12:01 a.m., local time, November 18, 2017, until January 1, 2018.

FOR FURTHER INFORMATION CONTACT: Kelli O'Donnell, NMFS Southeast Regional Office, telephone: 727–824–5305, email: *kelli.odonell@noaa.gov.*

SUPPLEMENTARY INFORMATION: The reef fish fishery of the Gulf includes gray triggerfish and is managed under the Fishery Management Plan for Reef Fish Resources of the Gulf (FMP). The FMP was prepared by the Gulf Fishery Management Council and is implemented under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622. All gray triggerfish weights discussed in this temporary rule are in round weight.

On August 4, 2008, NMFS established gray triggerfish accountability measures as well as commercial quotas for gray triggerfish through Amendment 30A to the FMP (73 FR 38139). On May 9, 2013, NMFS issued a final rule to implement Amendment 37 to the FMP (78 FR 27084). In part, Amendment 37 revised gray triggerfish commercial annual catch limits (ACLs) and ACTS.

Under 50 CFR 622.41(b)(1), NMFS is required to close the commercial sector for gray triggerfish when the commercial quota is reached, or is projected to be reached, by filing a notification to that effect with the Office of the Federal Register. NMFS has determined that the commercial quota for Gulf gray triggerfish of 60,900 lb (27,624 kg) will be reached by November 18, 2017. Accordingly, the commercial sector for Gulf gray triggerfish is closed effective 12:01 a.m., local time, November 18, 2017, until the start of the next commercial fishing season on January 1, 2018.

The operator of a vessel with a valid commercial vessel permit for Gulf reef fish having gray triggerfish onboard must have landed and bartered, traded, or sold such gray triggerfish prior to 12:01 a.m., local time, November 18, 2017. During the closure, the sale or purchase of gray triggerfish taken from the Gulf EEZ is prohibited. The prohibition on the sale or purchase does not apply to gray triggerfish that were harvested, landed ashore, and sold prior to 12:01 a.m., local time, November 18, 2017, and were held in cold storage by a dealer or processor.

The recreational sector for gray triggerfish is also closed through December 31, 2017. Therefore all harvest or possession of gray triggerfish is prohibited until the start of the new fishing year (50 CFR 622.39(b)). The commercial and recreational sectors for gray triggerfish will reopen on January 1, 2018, the beginning of the 2018 gray triggerfish fishing year.

Classification

The Regional Administrator, Southeast Region, NMFS, has determined this temporary rule is necessary for the conservation and management of gray triggerfish and the Gulf reef fish fishery and is consistent with the Magnuson-Stevens Act and other applicable laws.

This action is taken under 50 CFR 622.41(b)(1) and is exempt from review under Executive Order 12866.

These measures are exempt from the procedures of the Regulatory Flexibility Act because the temporary rule is issued without opportunity for prior notice and comment.

This action responds to the best scientific information available. The NOAA Assistant Administrator for Fisheries (AA), finds that the need to immediately implement this action to close the commercial sector for gray triggerfish constitutes good cause to waive the requirements to provide prior notice and opportunity for public comment pursuant to the authority set forth in 5 U.S.C. 553(b)(B), as such procedures are unnecessary and contrary to the public interest. Such procedures are unnecessary because the final rule implementing Amendment 37 (78 FR 27084; May 9, 2013), which established the closure provision for commercial gray triggerfish, have already been subject to notice and comment, and all that remains is to notify the public of the closure. Such procedures are contrary to the public interest because of the need to immediately implement this action to protect gray triggerfish since the capacity of the fishing fleet allows for rapid harvest of the commercial quota. Prior notice and opportunity for public comment would require time and could potentially result in a harvest well in excess of the established commercial quota.

For the aforementioned reasons, the AA also finds good cause to waive the 30-day delay in the effectiveness of this action under 5 U.S.C. 553(d)(3).

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 7, 2017.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2017–24519 Filed 11–9–17; 8:45 am]

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