

Send comments to Deborah Trunzo, SAMHSA Reports Clearance Officer, Room 16-105, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: September 17, 1997.

Richard Kopanda,

Executive Officer, SAMHSA.

[FR Doc. 97-25849 Filed 9-29-97; 8:45 am]

BILLING CODE 4162-20-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Mandatory Guidelines for Federal Workplace Drug Testing Programs

AGENCY: Substance Abuse and Mental Health Services Administration, HHS

ACTION: Revisions to the Mandatory Guidelines

SUMMARY: On November 16, 1995, the Department of Health and Human Services (HHS) published a notice in the **Federal Register** at 60 FR 57587 proposing to revise the Mandatory Guidelines for Federal Workplace Drug Testing Programs, 59 FR 29916 (June 9, 1994). Specifically, the Department proposed to change the drug testing levels for opiate metabolites and to require the testing for a metabolite of heroin in urine specimens collected as part of the Federal Workplace Drug Testing Program. After considering the comments, this Department is revising the Mandatory Guidelines to add such requirements. The goals of the revised new opiate testing policy are to substantially reduce the total number of specimens laboratories report positive for opiates that Medical Review Officers verify as negative, to shift the emphasis of testing for opiates back to the proper deterrence and detection of heroin use, and to reduce any unnecessary/excessive costs to drug testing without compromising the original drug deterrent objectives.

EFFECTIVE DATE: May 1, 1998.

FOR FURTHER INFORMATION CONTACT: Dr. Donna M. Bush, Chief, Drug Testing Section, Division of Workplace Programs, SAMHSA/CSAP, Room 13A-54, 5600 Fishers Lane, Rockville, Maryland 20857, tel. (301) 443-6014.

SUPPLEMENTARY INFORMATION: After considering comments received from the public, the Department is revising the guidelines entitled "Mandatory Guidelines for Federal Workplace Drug Testing Program," (Mandatory

Guidelines) which were initially published in the **Federal Register** on April 11, 1988 (53 FR 11979) and revised on June 9, 1994 (59 FR 29908). This revision and the Mandatory Guidelines are developed in accordance with Executive Order 12564 dated September 15, 1986, and section 503 of Public Law 100-71, 5 U.S.C. section 7301 note, the Supplemental Appropriations Act for fiscal year 1987 dated July 11, 1987. This revision incorporates changes based on the comments received during the public comment period and the Department's experience in implementing and administering these Mandatory Guidelines.

Background and Summary of Public Comments

A. Proposed Changes to the Testing Cutoff Levels for Opiates

The changes proposed in the notice published in the **Federal Register** on November 16, 1995, 60 FR 57587, are summarized here to facilitate the discussion of the comments received during the public comment period.

The Department proposed increasing the initial testing cutoff level for opiate metabolites and the confirmatory testing cutoff levels for morphine and codeine from 300 ng/mL to 2,000 ng/mL and establishing a new requirement to test for 6-acetylmorphine (6-AM), a metabolite that comes only from heroin, using a 10 ng/mL confirmatory level for specimens that have tested positive on the initial test.

The Department evaluated results on 1.1 million urine specimens tested for opiates in five certified laboratories and 317,500 specimens that were reviewed by three Medical Review Officer (MRO) groups. Based on the information obtained from the MROs, 87% of all opiate positives reported by the laboratories were verified as negatives by the MROs. The reasons given for reporting negative results included the use of prescription medications, poppy seed consumption, no clinical evidence of heroin use, or other unspecified reason. The reversal of most opiate positive results clearly indicates that the current opiate testing cutoff levels used by the laboratories are identifying too many individuals who are not opiate abusers. The 300 ng/mL testing levels had been selected to provide the greatest opportunity to identify anyone who may have used heroin. However, many who have not used heroin but had taken a prescribed codeine or morphine medication or eaten poppy seeds (which may contain morphine and/or codeine) have also tested positive. Since the

purpose of the workplace drug testing program is to deter and detect use of illegal drugs, establishing the testing cutoff levels for opiates at these higher levels will eliminate the identification of most individuals who are legitimately taking prescription medications that contain morphine or codeine or have ingested poppy seeds.

With regard to testing for 6-AM, the laboratory results indicate that of the approximately 1.1 million specimens tested, 7294 specimens were reported positive for codeine and/or morphine. Within this group of 7294 opiate positives, 848 were also tested for 6-AM and 16 of these 848 were reported positive for 6-AM. Of particular interest, was that 14 of these 16 6-AM positives had morphine concentrations greater than 2,000 ng/mL. In light of these results, the Department proposed to establish a requirement to test for 6-AM in specimens positive for opiates on the initial test because of the increased probability of detecting 6-AM when the morphine concentration was greater than 2000 ng/mL. Since 6-AM has a very short half-life (i.e., detectable for only a few hours after heroin use), it is essential that a laboratory use a sensitive analytical procedure to test for 6-AM. From the data available, it appears 10 ng/mL is the lowest testing level that can reasonably be used to consistently and accurately identify and quantitate the presence of 6-AM.

The Department believes that raising the testing levels for opiates and establishing a requirement to test for 6-AM will not reduce the deterrent value of the Federal Workplace Drug Testing Program. Additionally, the cost to Federal agencies may be reduced since there will be fewer specimens screened positive for opiates, fewer specimens sent to confirmatory testing, and fewer opiate positive results requiring extensive MRO review.

B. Public Comments and the Department's Response

The Department received 22 public comments on the proposed changes to the testing levels for opiates from individuals, companies, and laboratories. More than 50% of the commenters supported all or part of the proposed changes, while five commenters disagreed with the entire proposal. The remaining commenters expressed concern only with the implementation of a new policy and did not provide any comments to either support or disagree with the proposed changes. All written comments were reviewed and taken into consideration in setting the new testing levels. The substantive concerns raised in the

public comments and the Department's responses to the comments are discussed below. Similar comments are considered together.

1. Raising the Initial Testing Cutoff Level

More than 50% of the commenters supported raising the initial testing level for opiates as proposed. They agreed that the current initial testing level was unnecessarily identifying a large number of specimens as positive for opiates that were verified negative by the Medical Review Officer (MRO). Five commenters, however, were opposed to raising the initial testing level because it would no longer identify a number of individuals that misuse prescription medications that contain morphine or codeine. The Department recognizes that a very small percentage of individuals who abuse opiates that are currently reported positive using the 300 ng/mL initial test level would no longer be reported positive. However, the Department believes that the benefits from not reporting a large number of positives that are verified as negatives by an MRO outweigh the small risk of not detecting misuse of prescription drugs.

One commenter opposed deleting the footnote that had established an initial testing level of 25 ng/mL for free morphine and suggested a new level be established by applying the same factor that was used for the proposed opiate testing level. The Department disagrees with this comment. Since heroin, codeine, and morphine are excreted as varying concentrations of unchanged drug, glucuronide conjugates, and other metabolites, the Department believes it is more appropriate to use initial test kits that have a cross-reactivity with these metabolites rather than using a test kit that only detects free morphine. Because of this cross-reactivity, the Department believes it is appropriate to continue to list the initial test level as "opiate metabolites" rather than as morphine.

One commenter agreed that the initial test level should be raised, but suggested that the Department specify the analyte to be used for the test kit calibrators, that is, either morphine, morphine-3-glucuronide, or codeine. The Department agrees that the specific analyte used to calibrate a test kit has a direct impact on its ability to detect the presence of a drug or metabolite in a urine specimen. Therefore, test kit manufacturers should continue using morphine to prepare the calibrators for the revised opiate test kits as they had been using for the current opiate test kits.

2. Raise the Confirmatory Test Levels for Morphine and Codeine

The majority of the commenters agreed that raising the confirmatory test levels for morphine and codeine was appropriate and that the levels should correspond to the level established for the initial test. However, two commenters suggested that the confirmatory test level for morphine be raised to 4,000 ng/mL to make the test level consistent with that established by the Department of Defense (DoD) for its testing program. The Department does not agree that the two programs must use the same confirmatory testing levels. In light of the information found in the study of 1.1 million specimens noted above, the Department believes that the 2,000 ng/mL is the cutoff level that should be used at this time for agency testing.

3. Establish a Confirmatory Test Level for 6-Acetylmorphine

A majority of the commenters supported establishing a confirmatory test level for 6-acetylmorphine (6-AM); however, there was disagreement that it should be tested for on each specimen that was positive on the initial test. There were suggestions that a laboratory only test for 6-AM when the morphine concentration exceeds 2,000 or 4,000 ng/mL, or when the MRO requests a 6-AM analysis. Several commenters stated that testing for 6-AM on all presumptive positives places an unnecessary burden on the laboratory to conduct a second separate confirmatory test which will increase the cost of testing. In addition, there were suggestions that presumptive positives be tested only for 6-AM since the focus of the opiate testing is to identify heroin use. The Department believes that since the number of presumptive positives going to confirmation testing at a 2,000 ng/mL initial test level will be reduced significantly, there will not be a significant increase in the cost associated with testing for 6-AM. However, we do agree that testing for 6-AM on each presumptive positive may be unnecessary. Based on the pharmacology of heroin metabolism, 6-AM is likely present only when morphine is present in the specimen and its concentration exceeds 2,000 ng/mL. The concentration of codeine has no bearing on the possible presence of 6-AM. Therefore, the Department agrees with the commenters that 6-AM should only be tested for after a laboratory confirms that the morphine concentration exceeds 2,000 ng/mL rather than testing for 6-AM on each specimen that was positive on the initial test as had been proposed. In other

words, a positive codeine without morphine present or with morphine less than 2,000 ng/mL will not automatically require a test for 6-AM. The final revisions to the Mandatory Guidelines have been changed accordingly.

4. Implementation

Several commenters expressed concern that the new testing levels could not be implemented immediately because the test kit manufacturers will need sufficient time to reformulate their kits and to get them cleared by the Food and Drug Administration (FDA). Additionally, the laboratories will need time to validate new confirmatory test procedures using the new testing levels. The Department agrees that a sufficient time must be allowed for the new levels to be implemented and, therefore, the effective date is 180 days from the date of this publication.

Information Collection Requirements: There are no new paperwork requirements subject to the Office of Management and Budget approval under the Paperwork Reduction Act of 1980.

Dated: April 18, 1997.

Nelba Chavez,

Administrator, Substance Abuse and Mental Health Services Administration.

Dated: June 11, 1997.

Donna E. Shalala,

Secretary.

The following amendments are made to the Mandatory Guidelines for Federal Workplace Drug Testing Programs published on June 9, 1994 (59 FR 29916):

Subpart B

1. Section 2.4(e)(1), the initial test level for opiate metabolites appearing in the table, is amended by changing the value of "300" to "2,000" and deleting the footnote that had specified a 25 ng/mL testing level if the immunoassay test was specific for free morphine.

2. Section 2.4(f)(1), the confirmatory test level for morphine appearing in the table, is amended by changing the value of "300" to "2,000."

3. Section 2.4(f)(1), the confirmatory test level for codeine appearing in the table, is amended by changing the value of "300" to "2,000."

4. Section 2.4(f)(1), the table of confirmatory test levels, is amended by adding a new line under opiates to read as follows:

6-Acetylmorphine⁴ 10 ng/mL

5. Section 2.4(f)(1), the table of confirmatory test levels, is amended by

⁴ Test for 6-AM when the morphine concentration exceeds 2,000 ng/mL.

adding a new footnote under the table to read as follows:

[FR Doc. 97-25823 Filed 9-29-97; 8:45 am]
BILLING CODE 4160-20-U

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4285-N-01]

Debenture Recall

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: This notice announces a debenture recall of certain Federal Housing Administration debentures, in accordance with authority provided in the National Housing Act.

FOR FURTHER INFORMATION CONTACT: Richard Keyser, Room B133, Department of Housing and Urban Development, 451 Seventh Street, S.W., Washington, D.C. 20410, telephone (202) 755-7510. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: Pursuant to Section 207(j) of the National Housing Act, 12 U.S.C. 1713(j), and in accordance with HUD regulations at 24 CFR 207.259(e)(3), the Federal Housing Commissioner, with approval of the Secretary of the Treasury, announces the call of all Federal Housing Administration debentures, with a coupon rate of 6.75% or above, except for those debentures subject to "debenture lock agreements," that have been registered on the books of the Federal Reserve Bank of Philadelphia, and are, therefore, "outstanding" as of September 30, 1997. The date of the call is January 1, 1998.

The debenture will be redeemed at par plus accrued interest. Interest will cease to accrue on the debentures as of the call date. Final interest on any called debentures will be paid with the principal at redemption. During the period from the date of this notice to the call date, debentures that are subject to the call may not be used by the mortgagee for a special redemption purchase in payment of a mortgage insurance premium.

No transfer of debentures covered by the foregoing call will be made on the books maintained by the Treasury Department on or after October 1, 1997. This does not affect the right of the holder of a debenture to sell or assign the debenture on or after this date. Payment of final principal and interest due on January 1, 1998, will be made automatically to the registered holder.

Dated: September 25, 1997.

Nicolas P. Retsinas,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 97-25985 Filed 9-29-97; 8:45 am]

BILLING CODE 4210-27-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Endangered and Threatened Species Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications.

The following applicants have applied for permits to conduct certain activities with endangered species. This notice is provided pursuant to section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531, *et seq.*).

PRT-834589

Applicant: R.D. Zande & Associates, Inc., Columbus, Ohio; Robert F. Madej, principal investigator.

The applicant requests a permit to take (capture and release; survey hibernacula) gray bat (*Myotis grisescens*) and Indiana bat (*Myotis sodalis*); take (capture and release; collect one voucher specimen per site) American burying (=giant carrion) beetle (*Nicrophorus americanus*); take (capture and release) Hine's (=Ohio) emerald dragonfly (*Somatochlora hineana*); and take (survey habitat) Mitchell's satyr butterfly (*Neonympha mitchellii mitchellii*) throughout their ranges. Activities are proposed to document presence or absence of the species for the purpose of survival and enhancement of the species in the wild.

PRT-834596

Applicant: 3D/International, Inc. Environmental Group, Cincinnati, Ohio.

The applicant requests a permit to take (capture and release; collect empty shells) clubshell mussel (*Pleurobema clava*) and northern riffleshell mussel (*Epioblasma torulosa rangiana*) and to take (capture and release) American burying (=giant carrion) beetle (*Nicrophorus americanus*) and Hine's (=Ohio) emerald dragonfly (*Somatochlora hineana*) at Wright Patterson Air Force Base, Ohio. Activities are proposed to document presence or absence of the species for the purpose of survival and enhancement of the species in the wild.

Written data or comments should be submitted to the Regional Director, U.S.

Fish and Wildlife Service, Ecological Services Operations, 1 Federal Drive, Fort Snelling, Minnesota 55111-4056, and must be received on or before October 30, 1997.

Documents and other information submitted with these applications are available for review by any party who submits a written request for a copy of such documents to the following office within 30 days of the date of publication of this notice: U.S. Fish and Wildlife Service, Ecological Services Operations, 1 Federal Drive, Fort Snelling, Minnesota 55111-4056. Telephone: (612/725-3536 x224); FAX: (612/725-3526).

Dated: September 26, 1997.

John A. Blankenship,

Assistant Regional Director, IL, IN, MO (Ecological Services), Region 3, Fort Snelling, Minnesota.

[FR Doc. 97-25908 Filed 9-29-97; 8:45 am]

BILLING CODE 4310-55-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Availability of Draft Recovery Plan for Oahu Plants

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of document availability.

SUMMARY: The U.S. Fish and Wildlife Service (Service) announces the availability for public review of a draft Recovery Plan for Oahu Plants. There are 66 plant taxa included in this plan, all listed as endangered. All 66 taxa are endemic to Hawaii. Sixty are restricted to the island of Oahu and six occur on Oahu and other main Hawaiian Islands.

DATES: Comments on the draft recovery plan received by December 29, 1997 will be considered by the Service.

ADDRESSES: Copies of the draft recovery plan are available for inspection, by appointment, during normal business hours at the following locations: U.S. Fish and Wildlife Service, Pacific Islands Office, 300 Ala Moana Boulevard, Room 3108, Box 50088, Honolulu, Hawaii 96850 (phone 808/541-3441); and Hawaii State Library, 478 S. King Street, Honolulu, Hawaii 96813. Requests for copies of the draft recovery plan and written comments and materials regarding this plan should be addressed to Brooks Harper, Field Supervisor, Ecological Services, at the above Honolulu address.

FOR FURTHER INFORMATION CONTACT: Scott Johnston, Fish and Wildlife Biologist, at the above Honolulu address.