

specialists in the care of HIV-infected infants, children and adolescents, family members of HIV-infected children, and governmental agency representatives was convened by the National Pediatric and Family HIV Resource Center (NPHRC), sponsored by the Health Resources and Services Administration (HRSA), on July 9 and 10, 1997, to establish and finalize a new set of guidelines for the treatment of HIV-infected infants, children and adolescents. The Working Group was co-chaired by Dr. James Oleske, University of Medicine and Dentistry of New Jersey (UMDNJ)-New Jersey Medical School, Newark, NJ and Dr. Gwendolyn Scott, University of Miami, Miami, FL. The treatment recommendations provided in this document are based on published and unpublished data on HIV infection and treatment in adults and children and, when no definitive data were available, the consensus of the Working Group participants in the treatment of pediatric HIV infection. It is the intent of the Working Group that the guidelines be regarded as flexible and not supplant the clinical judgement of experienced health care providers. It is recognized that these guidelines will need to be modified as new information and experience become available.

Dated: September 24, 1997.

Claude Earl Fox,

Acting Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Statement of Organization, Functions, and Delegations of Authority

Part N, National Institutes of Health, of the Statement of Organization,

Functions, and Delegations of Authority for the Department of Health and Human Services (40 FR 22859, May 27, 1975, as amended most recently at 62 FR 37587, July 14, 1997, and redesignated from Part HN as Part N at 60 FR 56605, November 9, 1995), is amended as set forth below to reflect the reorganization of the National Library of Medicine as follows: The functional statements of the Division of Extramural Programs (DEP) and the DEP's Office of the Director are updated to reflect current responsibilities.

Section N-B, Organization and Functions, under the heading National Library of Medicine (NL, formerly HNL), is amended as follows: Delete the functional statements in their entirety for the Division of Extramural Programs (NL5, formerly HNL5) and its Office of the Director (NL51, formerly HNL51) and replace them with the following:

Division of Extramural Programs (NL5, formerly HNL5) (1) Administers programs to augment and strengthen the health sciences libraries of the Nation and to improve biomedical communications and information management through grants to, or contracts with, non-Federal and private institutions; (2) analyzes and evaluates extramural programs in relation to program objectives and national needs to achieve balanced and effective support; and (3) provides grants management, grants processing, and administrative management services.

Office of the Director (NL51, formerly HNL51) (1) Plans, directs, and administers the operations of the extramural programs; (2) coordinates collaborative efforts with other NIH components and Federal agencies in the general areas of informatics, information management, networking, health library support, and publications; and (3) provides technical and management assistance to advisory and review committees.

Dated: September 19, 1997.

Ruth Kirschstein,

Acting Director, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a list of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301)443-0525.

1998 National Household Survey on Drug Abuse —Revision—The National Household Survey on Drug Abuse (NHSDA) is a survey of the civilian, noninstitutionalized population of the United States, age 12 and over. The data are used to determine the prevalence of use of cigarettes, alcohol, and illicit substances, and illicit use of prescription drugs. The results are used by SAMHSA, ONDCP, Federal government agencies, and other organizations and researchers to establish policy, direct program activities, and better allocate resources. For 1998, the core NHSDA questionnaire will remain unchanged. Special topic modules related to substance abuse prevention have been added. The total annual burden estimate is 34,662 hours as shown below:

Instrument	No. of respondents	Responses/respondent	Hours/response	Total hour burden
Screening Form	82,741	1	0.050	4,137
Questionnaire and Verification Form	25,089	1	1.200	30,107
Screening Verification	2,482	1	0.067	166
Interview Verification	3,763	1	0.067	252
Total	34,662

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Dan Chenok, Human Resources and Housing Branch, Office of Management

and Budget, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Substance Abuse and Mental Health Services Administration Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork

Reduction Act of 1995 to provide the opportunity for public comment on proposed information collection activities, the Substance Abuse and Mental Health Services Administration publishes periodic summaries of proposed activities. To request more information on the proposed activities or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443-0525.

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including

whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

(1) Substance Abuse Prevention and Treatment Block Grant—45 CFR Part 96—Extension with no change—This interim final rule provides guidance to

States regarding the Substance Abuse Prevention and Treatment Block Grant legislation. The rule implements the reporting and recordkeeping requirements of 42 U.S.C. 300x 21-35 & 51-64 by specifying the content of the States' annual report on and application for block grant funds. The reporting burden hours will be counted towards the total burden for the FY 1999 SAPT Block Grant Application Format for which separate OMB approval will be requested. The total annual reporting and recordkeeping burden estimate is shown below:

	No. of respondents	Responses/respondent	Hours/response	Total hour burden
Reporting Burden—45 CFR 96				
Annual Report:				
96.122(f)	60	1	152	9120
96.134(d)	60	1	16	960
State Plan:				
96.122(g)	60	1	162	9720
96.124(c)(1)	60	1	40	2400
96.127(b)	60	1	8	480
96.131(f)	60	8	480
96.133(a)	60	1	80	4800
Waivers ¹ :				
96.132(d)	60	1	16	960
96.134(b)	60	1	40	2400
96.135(d)	60	1	8	480
Total Reporting Burden	60	1	530	31,800
Recordkeeping Burden—45 CFR 96				
96.129(a)(13)	60	1	16	960

¹ For the purpose of burden calculation, it is assumed that all States would apply for each waiver. In reality it expected that only a small number will apply.

(2) Tobacco Regulation for Substance Abuse Prevention and Treatment—45 CFR 96—Extension with no change—This final rule provides guidance to States regarding compliance with section 1926 of the Public Health Service Act related to sale and distribution of tobacco to minors. The final rule implements section 1926 by specifying annual reporting requirements to be in compliance with this section. The reporting burden shown below represents the average total hours to assemble, format, and produce the block grant provision on minors' access to tobacco, in accordance with the requirements of 45 CFR 96. These burden hours will be counted towards the total burden for the FY 1999 SAPT Block Grant Application Format for which separate approval will be requested.

	No. of respondents	Responses/respondent	Hours/response	Total hour burden
Annual Report: 96.122 (f)	59	1	0	¹ 0
96.130(e) (1-3)	59	1	15	885
State Plan:				
96.122 (g) (21)	0	0	0	² 0
96.130 (e) (4,5)	59	1	14	826
96.130 (g)	59	1	5	295
Total	34	2,006

¹ This section describes requirements for the first applicable year. For seven States, FY 1995 was the first applicable year. States are required to provide a copy of the statute enacting the law and are asked to provide a description of the previous year's activities, if they so desire. For the second and subsequent fiscal years, States are to provide a copy of any amendments. No burden is associated with these requests.

² This section duplicates the information collection language in section 96.130(e). The burden is shown for 96.130(e).

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.

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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