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Final
Notice
of
Proposed
Rulemaking

Part XI

Department of
Health and Human
Services

45 CFR Part 96
Substance Abuse Prevention and
Treatment Block Grants, Interim Final
Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 96

Substance Abuse Prevention and Treatment Block Grants

AGENCY Substance Abuse and Mental Health Services Administration PHS HHS

ACTION Interim Final Rule

SUMMARY Sections 1921 to 1954 of the Public Health Service (PHS) Act authorize the Secretary to provide Block Grants to States for the purposes of prevention and treatment of substance abuse which includes alcohol and other drugs. Among other things the Act requires that the funding agreements with the States provide for a number of provisions relating to intravenous substance abuse, tuberculosis and human immunodeficiency virus (HIV) testing and services, group homes for recovering substance abusers, and peer review requirements. This interim final rule establishes standards specifying the circumstances in which the Secretary will consider an application for a grant under section 1921 of the PHS Act to be in accordance with the law.

DATES *Effective Date* March 31 1993

Comment Date The Secretary is requesting written comments which must be received on or before (insert date 60 days after publication)

ADDRESSES Written comments on this interim final rule may be sent to Susan L. Becker, Director, Division of State Programs, Center for Substance Abuse Treatment (CSAT), Rockwall II Building, 10th Floor, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT Susan L. Becker, telephone No. (301) 443-3820.

SUPPLEMENTARY INFORMATION Sections 1921 to 1954 of the PHS Act, 42 U.S.C. 300x-21-300x-35, provide for allotments each year to States for the purposes of planning, carrying out and evaluating activities to prevent and treat substance abuse which is defined at section 96121 to include the abuse and/or illicit use of alcohol and other drugs. The Block Grant funds may be expended to provide for a wide range of activities to prevent and treat substance abuse and may be expended to deal with the abuse of alcohol, the use or abuse of illicit drugs, the abuse of licit drugs, and the use or abuse of tobacco products.

In order for the Secretary to award Block Grants, the States and eligible Indian tribes must apply for the Block

Grant and the application must be in accordance with the law. These interim final regulations establish standards specifying the circumstances in which the Secretary will consider an application for a grant to be in accordance with the law. Based on the criteria established in law and implemented by this regulation, there is only one Indian tribe that is currently eligible for funds under this program.

All of the statutory requirements for the Substance Abuse Prevention and Treatment Block Grant are applicable to fiscal year 1993 Block Grants, except section 1926 of the PHS Act. It is the Department's view that good cause exists to show that notice and comment are impracticable, or contrary to the public interest, 5 U.S.C. 553(b)(B) since pursuant to section 1932(d) of the PHS Act, Block Grant funds for substance abuse may not be provided to States for fiscal year 1993 on or after January 1, 1993 if the rule is not issued. These Block Grants are the major source of Federal funds to States to be used to establish and supplement various substance abuse prevention and treatment programs and an interruption or a delay in such funding could have a profound impact on the States' ability to provide substance abuse prevention and treatment, a result which is contrary to the War on Drugs and the public interest.

For similar reasons, this regulation is effective immediately. Delaying the effective date for a period of thirty days is contrary to the public interest. Requiring States that have submitted an acceptable application to wait an additional thirty days for payment would only compound the problem of delay and burden the States further in their provision of substance abuse prevention and treatment programs. Although the regulations are published as an interim final rule and are effective immediately, the Secretary requests comments on the regulations and is particularly interested in comments on alternative ways the law may be implemented. The Secretary will consider all comments and, after such consideration, make any amendments to the regulations by January 1, 1994, in a final rule.

The Application and Assurances

45 CFR 96.122 and 96.123 are added to describe what is to be provided in the application and the necessary assurances that the States (which includes the District of Columbia and the territories) will provide to ensure the Secretary that it will carry out the purposes of and expend the Block Grant in accordance with the law. In applying

for Block Grants for fiscal year 1993, applicants must submit an application containing information which conforms to all of the elements of the regulations.

Beginning in fiscal year 1994, applicants are required to use the standard application form prescribed by HHS with the approval of the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980. Upon submission to OMB for review, a copy of this application may be obtained from the Center for Substance Abuse Treatment, Division of State Programs, Rockwall II Bldg. 5600 Fishers Lane, Rockville, MD 20857. The contract person is Susan L. Becker. The Secretary has had preliminary discussions and will have further discussions with General Accounting Office (GAO) and the States about the reporting requirements under section 1942(a) of the PHS Act which is part of the application. However, the public is encouraged to formally comment on all of the information collection requirements contained in the standard form under the Paperwork Reduction Act. These comments will be carefully considered by OMB and the Secretary and, as a result of these comments, any changes to the rule will be made by January 1, 1994, or shortly thereafter.

The State in its application, as required by section 1932(a) of the PHS Act, is to submit the necessary assurances, as well as the State plan and the report required by sections 1932(b)(1) and 1942(a) of the PHS Act, respectively. Section 1932(b)(1) of the PHS Act provides that the States are to submit a State plan describing how the State plans to implement the requirements of the Act, such as those relating to the provision of tuberculosis and HIV services and services to pregnant women which are described in more detail below. It also provides that the States are to describe how the Block Grant is to be expended. 45 CFR 96.122(g) sets forth the information States are to provide the Secretary under the State plan.

Section 1942(a) of the PHS Act requires the States to submit a report which describes the purposes for which the grant received by the State for the preceding fiscal year was expended, a description of the activities of the State under the program, and the recipients of amounts provided in the grant. 45 CFR 96.122(f) sets forth the information that is to be submitted to the Secretary in the report.

In addition, the regulations applicable to the report require States to submit information on the use of Block Grant funds over a several year period. For example, for fiscal year

1993 specific information is to be submitted for Federal fiscal years 1990 1991 and 1992 as well as for the most recent twelve month State expenditure period for which expenditure information is available. Information from earlier years is necessary because it often takes States two to three years to acquire actual expenditure and other data. The Secretary believes it is essential that actual data (rather than simply estimates) be acquired for monitoring the Block Grant funds to ensure that the funds are expended for authorized purposes and in accordance with the law.

Also when information is requested for fiscal years 1990 1991 and 1992 applicants are to provide information relating to substance abuse prevention and treatment activities under the Alcohol Drug Abuse and Mental Health Services (ADMS) Block Grant formerly authorized by sections 1911 and 1926 of the PHS Act. Although those sections have been amended the Department will review those expenditures to ensure that the Block Grant funds were expended in accordance with the law in effect for those fiscal years.

As has been the case under the ADMS Block Grant, the funding agreements and assurances in the application are to be made through certification by the chief executive officer personally or by an individual authorized to make such certification on behalf of the chief executive officer. If a delegation has occurred a copy of the current delegation of authority must be submitted with the application.

The application (in substantial compliance with the statutory and regulatory provisions) is to be submitted for fiscal year 1993 no later than ninety days after publication of these regulations and for subsequent years no later than March 31 of the fiscal year for which the State is applying for funds. The Secretary believes this will allow States sufficient time to complete the applications and as to the March 31 deadline allow for a more orderly process. The term fiscal year refers to the Federal fiscal year. This will make the HHS review process more efficient and may expedite the process of reviewing applications and awarding the grants.

The Secretary will approve an application with a State plan, assurances and report which satisfy the requirements of the Act and the regulations. The State is required to provide descriptions of how the State is implementing the provisions of the Act and the regulations. Unless provided otherwise by the regulations the Secretary will approve procedures

which are provided as examples in the regulations or the State may submit other procedures which the Secretary determines to reasonably implement the requirements of the Act and the regulations.

Certain Allocations and Primary Prevention

45 CFR 96.124 and 96.125 are added to implement the provisions of Section 1922 of the PHS Act which requires States to expend the Block Grant on various programs. Specifically the State is required to expend not less than 35 percent of the Block Grant for prevention and treatment activities regarding alcohol and not less than 35 percent for treatment and prevention activities relating to other drugs.

In addition not less than 20 percent of the grant is to be expended for primary prevention activities. Section 96.125 is added which requires States to develop a comprehensive prevention program which provides a broad array of prevention activities and services including such activities and services to discourage the use of alcoholic beverages and tobacco products by minors. These activities and services must be provided in a variety of settings for both the general population as well as targeted subgroups who are at high risk for substance abuse. Section 96.125 provides examples of strategies the States may use in developing a comprehensive primary prevention program. Under each strategy examples of acceptable programs are listed.

The Secretary believes the examples of acceptable strategies and activities are important to alleviate any confusion in the prevention field as to acceptable primary prevention activities under the Block Grant. This is particularly important because of the major change in how prevention for purposes of the 20 percent set aside is defined in the Block Grant—that is primary prevention *only* as compared to prevention and early intervention.

It should be noted however that the primary prevention definition is for purposes of the "Substance Abuse Prevention and Treatment Block Grant regulations *only*. This definition does not apply to other programs administered by SAMHSA or the Center for Substance Abuse Prevention such as the High Risk Youth programs which include intervention activities which go beyond activities authorized by these regulations.

The Secretary assures States that early intervention activities which counted as part of the 20 percent prevention set aside prior to passage of the Alcohol Drug Abuse and Mental Health

Administration Reorganization Act—Public Law 102-321 July 10 1992 are allowable activities under the Block Grant but do not now count as primary prevention.

Section 96.124 implements section 1922 of the PHS Act which provides for specific allocations to increase the availability of treatment services designed for pregnant women and women with dependent children. Under § 96.124 the State is required to expend not less than 5 percent of the fiscal year 1993 grant to increase (relative to fiscal year 1992) such services consistent with the base described in § 96.124(c). This requirement may be waived upon the request of the State if the Secretary determines that the State is providing an adequate level of services for this population. In determining whether an adequate level does exist, the Secretary will review the extent to which a State is providing services to this population and will consider whether the minimum level of services stipulated in § 96.124(e) are being provided for pregnant women and women with dependent children who are being served.

At a minimum the Secretary requires States to ensure that treatment programs receiving funding from the Block Grant set aside for pregnant women and women with dependent children for such services also provide or arrange for the following: (1) Primary medical care for women who are receiving substance abuse services including prenatal care and while women are receiving such treatment child care; (2) primary pediatric care for their children including immunizations; (3) gender-specific substance abuse treatment and other therapeutic interventions for women that may address issues of relationships sexual and physical abuse and parenting and child care while the women are receiving these services; (4) therapeutic interventions for children in custody of women in treatment which may among other things address their developmental needs and their issues of sexual and physical abuse and neglect; and (5) sufficient case management and transportation services to ensure that women and their children have access to the services provided by (1) through (4).

Because of the important health issues relating to the provision of treatment services to pregnant women and women with dependent children the Secretary strongly encourages the States to require all programs that provide services to women to also provide a comprehensive range of services to such women and their children either directly or through linkages with community based organizations. These services include

case management to assist in establishing eligibility for public assistance programs provided by Federal State or local governments employment and training programs education and special education programs drug free housing for women and their children prenatal care and other health-care services therapeutic day care for children Head Start, and other early childhood programs.

In addition to providing the minimum services, the State is to require that all programs which provide substance abuse treatment services to pregnant women and women with dependent children using funds from the Block Grant amount set aside for such purposes must treat the family as a unit and therefore admit both women and their children into treatment when appropriate. Such an admission may not be appropriate however if for example the father of the child is able to adequately care for the child. In addition the amount set aside for such services must be expended on individuals who have no other financial means in obtaining such services as provided by § 96.137. This is important so as to increase the level of service to pregnant women and women with dependent children.

Finally women with dependent children for the purposes of section 96.124 include women in treatment who are attempting to regain custody of their children. The Secretary believes that this is important, because often a court has custody of the children and regaining custody is dependent on successful substance abuse treatment. Regaining custody of their children may serve as an incentive to these women to successfully complete treatment and to remain alcohol and drug free.

Capacity of Treatment for Intravenous Substance Abusers

45 CFR 96.126 is added to implement section 1923 of the PHS Act which provides that as a condition of receiving Block Grant funding the State must require programs that receive funding under the grant and that treat individuals for intravenous substance abuse to inform the State when they reach 90 percent of capacity. The Secretary requires States as a condition of receipt of a grant, to establish a capacity management program which reasonably enables a program to readily report to the State when it reaches 90 percent capacity. The requirement for a capacity management system is an important change in the substance abuse and prevention block grant program and the Secretary requests comments on

efficient but cost effective means to implement this section.

In addition section 1923 of the PHS Act requires the State to ensure that each individual who requests and is in need of treatment for intravenous drug abuse be admitted to the program not later than 14 days after making the request for admission to such a program or 120 days after the date of such request, if no such program has the capacity to admit the individual on the date of such request and if interim services are made available to the individual not later than 48 hours after such request.

In carrying out these provisions the Secretary requires the State to establish a waiting list management program which provides systematic reporting of treatment demand. The State is to require any program receiving funding from the grant for the purposes of treating injecting drug abusers to establish a waiting list which includes a unique patient identifier for each injecting drug abuser seeking treatment including those receiving interim services while awaiting admission to such treatment. For individuals who cannot be placed in comprehensive treatment within 14 days the State is to ensure that individuals receive interim services and to develop a mechanism for maintaining contact with the individuals awaiting admission. Whatever mechanism is developed it must ensure that patients on waiting lists are transferred at the earliest possible time to a program providing treatment within a reasonable geographic area.

However if a person cannot be located for admission into treatment or if a person refuses treatment such individuals may be taken off the waiting lists and the States are not obligated to provide treatment to those individuals within 14 or 120 days whichever is applicable under § 96.126. The Secretary believes that to have a continuing obligation to provide treatment to such individuals would result in programs having unoccupied slots so as to be able to fulfill its obligations. This result, the Secretary believes would not promote treatment.

The Secretary is considering whether regulations should be issued requiring States not only to establish a capacity management program which will monitor available slots in treatment programs but to establish a central registry to track individuals so as to make available treatment in a timely fashion. A central registry may also be useful to make available treatment to pregnant women as provided in § 96.131. The Secretary seeks comments

on the central registry concept and any alternatives to a central registry.

Interim services for the purposes of section 96.126 may entail any number of services including interim methadone maintenance as authorized by section 1976 of the PHS Act and the applicable regulations. The Secretary however requires that at a minimum interim services include counseling and education about HIV and tuberculosis about the risks of transmission to sexual partners and infants and about steps that can be taken to ensure that HIV transmission does not occur as well as referral for HIV and TB treatment services, if necessary. For pregnant women the Secretary believes it is essential that interim services also include counseling on the effects of alcohol and drug use on the fetus as well as referrals for prenatal care. These provisions are consistent with the thrust of the Block Grant—to prevent the spread of HIV infection and to treat substance abuse.

Section 1923 of the PHS Act also requires States to ensure that any entity that receives funding for treatment services for intravenous drug abuse carry out activities to encourage individuals in need of such treatment to undergo such treatment. In carrying out this provision the Secretary requires the States to use outreach models that are scientifically sound so as to optimally maximize these outreach programs or if no such models are available which are applicable to the local situation to use an approach which reasonably can be expected to be an effective outreach method. Examples of scientifically sound models include the following: (1) The standard intervention model as described in *The NIDA Standard Intervention Model for Injection Drug Users Intervention Manual*, National AIDS Demonstration Research (NADR) Program National Institute on Drug Abuse Feb 1992; (2) the health education model as described in Rhodes F Humfleet, G.L. et al *AIDS Intervention Program for Injection Drug Users Intervention Manual* (Feb 1992) and (3) the indigenous leader model as described in Wiebel W Levin L.B *The Indigenous Leader Model Intervention Manual* (Feb 1992).

As part of the outreach programs the Secretary among other things also requires the States to ensure that such entities promote awareness among injecting drug abusers about the relationship between injecting drug abuse and communicable diseases and select train and supervise outreach workers. These measures ensure quality outreach programs and will prevent the

use of less effective strategies such as simply having persons without an understanding of substance abuse handing out flyers

Requirements Regarding Tuberculosis and HIV

45 CFR 96 127 and 96 128 are added to provide for the provisions of section 1924 of the PHS Act regarding tuberculosis and HIV treatment services. Under the PHS Act, States are to require any entity receiving amounts from the Block Grant for operating a program of treatment for substance abuse (1) to directly or through arrangements with other public or nonprofit private entities, routinely make available tuberculosis services as defined in section 96 121 to each individual receiving treatment for such abuse and (2) in the case of an individual in need of such treatment who is denied admission to the program on the basis of the lack of the capacity of the program to refer the individual to another provider of tuberculosis services.

In carrying out this tuberculosis provision the Secretary requires that the principal agency of a State in consultation with the State Medical Director for Substance Abuse Services and in cooperation with the Tuberculosis Control Officer of the State Department of Health, develop written procedures to implement these provisions, as well as protocols to be implemented by the programs to prevent the transmission of tuberculosis such as screening patients. In addition the principal agency is to develop a plan establishing linkages with other health providers to ensure that tuberculosis services are routinely made available

The Secretary is requiring the State to also develop an effective system for monitoring program compliance with this section. This system should be developed in conjunction with those systems required for services to injecting drug abusers under section 96 126(b) and for ensuring that services are being provided to pregnant women under section 96 131(f). The Secretary believes it is critical that pregnant women who are addicts be provided substance abuse and other treatment as early as possible both because of the health of the mother and the effects of the addiction on the fetus. Close monitoring is thus important to insure compliance by treatment providers. The Secretary also believes that tuberculosis and HIV are health problems of enormous consequence and therefore programs must be monitored closely to ensure provision of such

services in accordance with the regulation. Although the regulation does not prescribe a system for monitoring the provision of these services the States are to develop effective systems that will ensure to the maximum extent possible that these services are being provided. The State may wish to consider routine inspections of providers as a way of carrying out this requirement. The Secretary seeks comments on procedures to implement these provisions that will be both efficient and cost effective.

As to HIV some States are to carry out one or more projects to make available to individuals early intervention services for HIV disease as defined by section 96 121 at the sites at which the individuals are undergoing treatment. This requirement is applicable only to a State whose rate of cases of acquired immune deficiency syndrome is 10 or more such cases per 100 000 individuals (as indicated by the number of such cases reported to and confirmed by the Director of the Centers for Disease Control for the most recent calendar year for which the data are available) and the amount to be expended is the amount prescribed at section 1924 of the PHS Act.

Further if the State plans to carry out 2 or more such projects the State is to carry out one of the projects in a rural area of the State unless the requirement is waived. The Secretary will waive the requirement if the State certifies to the Secretary that there is insufficient demand in the State to carry out a project in any rural area or there are no rural areas in the State.

The Secretary requires the State to ensure that the programs participating in the project establish linkages with a comprehensive community resource network of related health and social services organizations to ensure a wide-based knowledge of the availability of these services and to facilitate referral. All individuals with active TB shall be reported to the appropriate State official as required by State law.

Section 1924(b)(6) of the PHS Act also requires States to ensure that with respect to the provision of early intervention services for HIV disease to an individual such services will be undertaken voluntarily by and with the informed consent of the individual and undergoing such services will not be required as a condition of receiving treatment services for substance abuse or any other services. Designated States are to establish a plan to carry out these provisions and are required to develop effective strategies for monitoring program compliance with this section.

As to both TB and HIV services section 1924 of the PHS Act requires that the Block Grant be used for such services as payor of last resort. Furthermore for both HIV services (if a designated State) and TB services, the State is to maintain Statewide expenditures (rather than expenditures only through the principal agency) of non Federal amounts for such services at a level that is not less than the average level of such expenditures maintained by the State for a 2 year period preceding the first fiscal year for which the State receives such a grant. The Secretary requires States to establish a reasonable funding base for fiscal year 1993 and use the defined base consistently in establishing future compliance with this section.

Revolving Funds for Establishment of Homes in Which Recovering Substance Abusers May Reside

45 CFR § 96 129 is added to implement requirements relating to the revolving funds for the establishment of homes in which recovering substance abusers may reside. These requirements however do not apply to any territory of the United States other than the Commonwealth of Puerto Rico.

Section 1925 of the PHS Act requires that the State establish and provide for the ongoing operation of a revolving fund for the purpose of making loans for the costs of establishing programs for the provision of housing in which individuals recovering from alcohol and drug abuse may reside in groups of not less than six individuals. Not less than \$100 000 is to be available for the revolving fund and loans made from the revolving fund are not to exceed \$4,000. The loans are to be repaid to the revolving fund not later than 2 years after the date on which the loan is made and each such loan is to be repaid by such residents through monthly installments by the date specified in the loan agreement involved. Such loans are made only to nonprofit private entities agreeing to a number of provisions including that in the operation of the program established pursuant to the loan the use of alcohol or any illegal drug in the housing provided by the program will be prohibited and the costs of the housing including fees for rent and outlets will be paid by the residents of the housing.

In addition the Secretary has provided further requirements that States are to follow to ensure the integrity of the program and to place borrowers on notice of what is expected of them. The Secretary expects the State to (1) identify and clearly define legitimate purposes for which funds

be spent (2) establish reasonable criteria for selecting a fund management group if the State plans to indirectly manage the fund (3) set reasonable criteria in determining the eligibility of prospective borrowers (4) establish a procedure and process for applying for a loan under the program (5) provide clear written instructions to applicants concerning what is expected of them such as timelines required documentation and notification of reasonable penalties and recourse for default, and (6) keep a written record of the number of loans and amount of loans provided the identities of borrowers and the repayment history of each borrower For instructional information on group homes refer to *Self Run Self Supported Houses for More effective Recovery from Alcohol and Drug Addiction* DHHS Publication No (ADM) 90-1678 (1990) which is available through the National Clearinghouse for Alcohol and Drug Information (NCADI)

Treatment Services for Pregnant Women

45 CFR 96 131 is added to implement regulations for treatment services for pregnant women as required by section 1927 of the PHS Act Section 1927 requires the State to ensure that each pregnant woman in the State who seeks is referred for and would benefit from such services is given preference in admissions to treatment facilities receiving funds pursuant to the grant In carrying out this provision the Secretary requires the State to ensure that the availability of treatment to pregnant women is publicized by public service announcements (radio/television) or street outreach programs

In addition the Secretary requires the State to ensure that entities that serve women and who are receiving such funds provide preference to pregnant women The State shall require that programs which serve an injecting drug abuse population and who receive Block Grant funds shall give preference to treatment as follows (i) pregnant injecting drug users (ii) pregnant substance abusers (iii) injecting drug users and (iv) all others The Secretary believes it is essential that pregnant women receive preferential treatment because of the added risk to the fetus of contracting HIV from the mother's use of injecting drugs

The State is to also require that a facility which serves women refer pregnant women to the State if the treatment facility has insufficient capacity to provide treatment services to any such pregnant woman who seeks the services from the facility The Secretary proposes that this may be

accomplished by establishing a toll free number or other reasonable means to implement this provision

The State is to then refer the pregnant woman to a treatment facility that has the capacity to provide treatment services to the pregnant woman or if on treatment facility has the capacity to admit the pregnant woman to make available interim services as defined in § 96 121, to the pregnant woman not later than 48 hours after she seeks the treatment services This means that the State is required to have a capacity tracking system which tracks all open treatment slots available to pregnant women in the State Such a system must be continually updated to identify treatment capacity for any such pregnant woman The State may wish to coordinate the capacity tracking system required under § 96 131 with the capacity tracking system required under § 96 126 for injecting drug abusers

Procedures for the implementation of this section are to be developed in consultation with the State Medical Director for Substance Abuse Services The State is also to develop effective strategies for monitoring program compliance with § 96 131

Additional Agreements

45 CFR 96 132 is added to implement sections 1928 and 1943(b) of the PHS Act regarding additional requirements relating to substance abuse With respect to individuals seeking treatment services the State is required to improve (relative to fiscal year 1992) the process in the State for referring the individuals to treatment facilities that can provide to the individuals the treatment modality that is most appropriate for the individuals The regulations provide examples of ways to implement this provision including the utilization of a toll free number for programs to report available capacity and waiting list data and/or the implementation of a capacity management/waiting list management system

With respect to any facility for treatment services or prevention activities that is receiving amounts from a Block Grant, continuing education in such services or activities (or both as the case may be) is to be made available to employees of the facility who provide the services or activities The States are to require programs to include a provision in its funding agreement with the State concerning continuing education for employees of the facility

The State is to coordinate prevention and treatment activities with the provision of other appropriate services (including health social correctional

and criminal justice education vocational rehabilitation and employment services) The regulations specify that the Secretary in monitoring compliance with this section will consider such factors as the existence of memoranda of understanding between various service providers or agencies and evidence that the State has included prevention and treatment service coordination in its grants and contracts. The Secretary believes that improving service coordination and integration of services is an important objective It is particularly important in the area of substance abuse because many of the individuals involved are either served by or need to receive services from a variety of systems The Secretary is interested in receiving comments about additional ways that might be used to strengthen the service coordination provision For example should States be required to have an internal mechanism for monitoring service coordination such as receiving reports from treatment programs that do not get cooperation from other service systems? Should preference be given to funding treatment programs that do make arrangements for service coordination?

Section 1928 of the PHS Act also provides for a waiver at the request of the State of any or all of the requirements established above but only if the Secretary determines that, with respect to services for the prevention and treatment of substance abuse the requirement involved is unnecessary for maintaining quality in the provision of such services in the State In determining whether to grant a waiver the Secretary will rely on information drawn from the independent peer review/quality assurance activities conducted by the State and such other information as the Secretary deems necessary

Finally the State is required to have in effect a system to protect from inappropriate disclosure patient records maintained by the State in connection with an activity funded under the program involved or by any entity which is receiving amounts from the grant. The Secretary requires that the system is to include provisions for employee education on the confidentiality requirements and employees are to be informed of the fact that disciplinary action may occur upon inappropriate disclosures.

Submission to Secretary of Statewide Assessment of Needs

45 CFR § 96 133 is added to require a State to submit to the Secretary an assessment of the need in the State for authorized activities both by locality

d by the State in general as required / section 1929 of the PHS Act The assessment must include the incidence and prevalence in the State of drug abuse and the incidence and prevalence in the State of alcohol abuse and alcoholism Setting-up information systems to obtain such data may take time and will likely require technical assistance from HHS. Therefore in carrying out this provision, the Secretary requires the States to submit for fiscal years 1993 through 1996 its best available data on the incidence and prevalence of drug and alcohol abuse and alcoholism The State is also to provide a summary describing the weaknesses and bias in the data and a description on how the State plans to strengthen the data in the future

With regard to fiscal year 1997 and subsequent years the Secretary is considering requiring the States to provide incidence and prevalence data which is supported by quantitative studies using generally accepted methods of research. The State could determine the appropriate methodology to be used in gathering the information The data, however would have to be collected and reported by age sex and race/ethnicity and at the State level and at sub-State level (as defined by the State) The data at a minimum would have to be collected and reported on five code substance abuse problems marijuana (including hashish) cocaine (including Crack) hallucinogens (including PCP) heroin and alcohol The Secretary is also considering requiring the use of common diagnostic criteria for dependence that characterize the cluster of cognitive behavioral and physiological symptoms that indicate the person has impaired control of substance abuse and continues use of the substance despite adverse consequences The Secretary specifically requests comment on the barriers the State would face for fiscal year 1997 and subsequent years including the cost of such collection if these requirements were imposed The Secretary seeks reasonable alternatives that are consistent with legislation and are cost effective

Section 1929 of the PHS Act also requires the State to provide a detailed description of current prevention and treatment activities in the State. For fiscal year 1993 the State is required to provide its best available data on current prevention and treatment activities in the State in such detail as it finds reasonably practicable given its own data collection activities and records For fiscal years 1994 and subsequent years the Secretary requires that the report include a detailed

description of the intended use of the funds relating to prevention and treatment as well as a description of treatment capacity As to primary prevention activities, the activities must be broken down by strategies used, such as those provided in section 96 125 The State must provide the following data, if available the specific activities conducted, the specific risk factors being addressed by activity the age race/ethnicity and gender of the population being targeted by the prevention activity and the community size and type where the activity is carried out. As to all treatment and prevention activities including primary prevention, the State must provide the identities of the entities that provide the services and describe the services provided The State is to submit information on treatment utilization to describe the type of care and the utilization according to primary diagnosis of alcohol or drug abuse or a dual diagnosis of drug and alcohol abuse

Section 1929 of the PHS Act requires the State to also describe in detail its efforts to improve substance abuse treatment and prevention activities The Secretary requires that this report include the State's strategy to improve existing programs as well as a description of the new programs created activities taken to remove barriers and actions taken to improve such activities

Section 1929 of the PHS Act requires the State to submit a detailed description on the extent to which the availability of prevention and treatment activities is insufficient to meet the need for the activities the interim services to be made available under sections 96 126 and 96 131 and the manner in which such services are to be so available In carrying out this provision the Secretary requires the State to submit documentation describing the results of the State's management information system pertaining to capacity and waiting lists, as well as a summary of such information for admissions and when available discharges As to prevention activities the report must include a description of the populations at risk by risk factor gender age and ethnicity Populations at risk include among others children of substance abusers pregnant women school dropouts and homeless and run-away youth

Maintenance of Effort regarding State Expenditures

45 CFR 96 134 is added to implement section 1930 of the PHS Act which requires the principal agency of the

State to maintain aggregate State expenditures by the principal agency for authorized activities at a level that is not less than the average level of such expenditures maintained by the State for the two year period preceding the fiscal year for which the State is applying for the grant.

In addition to the maintenance of effort by the principal agency the Secretary requires the States not to use the Block Grant to supplant State funding of substance abuse prevention and treatment programs. The Secretary believes it is essential in combating the war on drugs and other substances that the Block Grant be expended to increase services rather than using the funds to maintain the current level of such programs.

The Secretary may upon a request by the State waive all or part of these requirements only if the Secretary determines that extraordinary economic conditions in the State justify the waiver If a waiver is issued it will be applicable only to the fiscal year involved. The Secretary defines

extraordinary economic conditions as a financial crisis in which the total tax revenue declines at least one and one-half percent, and either unemployment increases by at least one percentage point or employment declines by at least one and one half percent The Secretary seeks comments on this and other criteria.

In making a Block Grant to a State for a fiscal year the Secretary must also make a determination of whether for the previous fiscal year or years, the State maintained material compliance with all agreements made under this section If the Secretary determines that a State has failed to maintain such compliance the Secretary will reduce the amount of the allotment for the State for the fiscal year for which the grant is being made by an amount equal to the amount constituting such failure for the previous fiscal year

To support the maintenance of effort requirement States must provide the dollar amount reflecting the aggregate State expenditures by the principal agency for authorized activities for each of the two State fiscal years preceding the fiscal year for which the State is applying for the grant. The base must be calculated using Generally Accepted Accounting Principles and the composition of the base must be applied consistently from year to year

Restrictions on Expenditure of Grant

45 CFR 96 135 is added to implement section 1931 of the PHS Act which requires that States not expend the Block Grant on a number of activities

For example a State is not to expend grant money for inpatient hospital substance abuse programs except in the case that such treatment is a medical necessity for the individual involved and the individual cannot be effectively treated in a community based, nonhospital residential treatment program. If such circumstances occur section 1931 requires that the daily rate of payment provided to the hospital for providing the services cannot exceed the comparable daily rate provided by a residential treatment program.

In carrying out this section the Secretary allows grant funds to be used for this purpose only if a physician makes a determination that (1) The primary diagnosis of the individual is substance abuse and the physician certifies this fact (2) the individual cannot be safely treated in a community based nonhospital residential treatment program (3) the service can reasonably be expected to improve an individual's condition or level of functioning and (4) the hospital-based substance abuse program follows national standards of substance abuse professional practice. In addition grant money may be expended for such services only to the extent that it is medically necessary i.e. only for those days that the patient cannot be safely treated in a residential community based program.

Section 1931 of the PHS Act also provides that grant money may not be used to purchase or improve land purchase construct or permanently improve (other than minor remodeling) any building or other facility or purchase major medical equipment. The PHS Act provides however that the Secretary may grant a waiver to a requesting State of the restriction on expending a grant for the construction of a new facility or rehabilitation of an existing facility but not for land acquisition.

The Secretary may approve a waiver only if (1) the State demonstrates to the Secretary that adequate treatment cannot be provided through the use of existing facilities and that alternative facilities in existing suitable buildings are not available (2) the State has carefully designed a program that will minimize the costs of additional beds and (3) the State agrees with respect to the costs to be incurred by the State in carrying out the purpose of the waiver to make available non Federal contributions in cash toward such costs in an amount equal to not less than \$1 for each \$1 of Federal funds provided under section 1931. In granting a waiver the Secretary will allow the use of a specified amount of funds to

construct or rehabilitate a specified number of beds for residential treatment and a specified number of slots for outpatient treatment based on reasonable estimates by the State of the costs of construction or rehabilitation. Section 96 135 sets out the information that is needed to request a waiver.

Numerous other restrictions on expenditures of the grant are provided by law including expenditures on activities (1) to satisfy any requirement for the expenditure of non Federal funds as a condition for the receipt of Federal funds (2) to provide financial assistance to any entity other than a public or nonprofit private entity (3) to make payments to intended recipients of health services and (4) to carry out any program prohibited by section 256(b) of the Health Omnibus Programs Extension of 1988 (42 U.S.C. 300ee-5) relating to the provision of hypodermic needles to injecting drug users.

The State is also to limit expenditures on certain activities. The State is not to expend more than 5 percent of the grant to pay the costs of administering the grant. The State is not to expend the grant for the purpose of providing treatment services in penal or correctional institutions of the State. The State is not to expend more than an amount prescribed by section 1931(a)(3) of the PHS Act.

Independent Peer Review

45 CFR 96 136 is added which requires the State for the fiscal year which the grant is provided to provide for independent peer review to assess the quality appropriateness and efficacy of treatment services provided in the State to individuals under the program involved and ensure that at least 5 percent of the entities providing services in the State under such program are reviewed.

The purpose of independent peer review is to review the quality and appropriateness of treatment services. The review is to focus on treatment programs and the substance abuse service system rather than on the individual practitioners. The intent of the independent peer review process is to continuously improve the treatment services to alcohol and drug abusers within the State system.

The regulations require the independent peer reviewers to be individuals with expertise in the field of alcohol and drug abuse treatment. Because treatment services may be provided by multiple disciplines the individual peer reviewers must be representative of the various disciplines utilized. They must be knowledgeable about the treatment settings and differences in treatment approaches and must be

sensitive to cultural and environmental issues that may influence the quality of the services provided.

As part of the independent peer review the reviewers are required to review a representative sample of patient/client records to determine quality and appropriateness of treatment services as well as admission criteria/intake process assessments treatment planning documentation of implementation of treatment services and discharge and continuing care planning.

The regulations also require the State to ensure that the peer review will not involve practitioners or providers reviewing their own programs or programs in which they have administrative oversight, and ensure that there is a separation of peer review personnel from funding decisionmakers.

Direct Application for Grant by Indian Tribes

45 CFR 96 46(c) is amended to establish criteria prescribed by the Secretary as is required by section 1933(d)(3) of the PHS Act. It establishes criteria that Indian tribes or tribal organizations which are eligible for a direct grant must follow. Essentially these entities must abide by all the statutory provisions and accompanying regulations except for the following provisions of the PHS Act: section 1923 which relates to provisions on intravenous substance abuse; section 1925 which provides for group homes for recovering substance abusers; section 1926 regarding State laws on the sale of tobacco products to minors; section 1928 regarding funding agreements for improving referrals continuing education and coordination of activities in the State; section 1929 regarding submission of Statewide assessment of needs; and section 1943(a)(1) relating to peer review of treatment programs.

The Department believes these provisions are too burdensome for Indian tribes and not really feasible. The Department believes however that it is essential that these entities expend the funds for purposes for which they are intended and any Indian tribe or tribal organization that is eligible for a direct grant will be subject to the technical review requirements of section 1945(g) and the audit requirements of section 1942 of the PHS Act.

45 CFR 96 46 (a) and (b) are also amended to reflect technical changes such as statutory citation changes.

Economic Impact

In crafting these regulations the Secretary sought to minimize cost and

burden both to States and to service providers. The Secretary recognizes that there are a number of areas in which requirements are tougher compared to the predecessor Block Grant, either because of the statute or the Department's judgment as to what is needed for effective programs. In none of these areas however has the Secretary imposed any requirement which would increase cost drastically or unreasonably. Nor does the Secretary believe that a well run service program should have a major difficulty in meeting the new requirements. For example, an astutely designed outreach program can be operated effectively without incurring many additional hours of effort in most circumstances. However, the Secretary welcomes

comment on cost or burden and will seek to eliminate any unnecessarily costly provisions in the final rule.

For these reasons, this rule does not have cost implications for the economy of \$100 million or otherwise meet the criteria for a major rule under Executive Order 12291 and therefore does not require a regulation impact analysis. Further, these regulations will not have a significant impact on a substantial number of small entities and therefore do not require a regulatory flexibility analysis under the Regulatory Flexibility Act of 1980.

Paperwork Reduction Act

This proposed rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under

the Paperwork Reduction Act of 1980. The title, description, and respondent description applicable to the information collection requirements are shown below with an estimate of the annual reporting and record keeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Substance Abuse Prevention and Treatment Block Grant.

Description: This action requires States to annually submit an application for allotments under a formula grant to the States.

Description of Respondents: State or local governments.

Section	Number of respondents	Number of responses per year	Number hours per response	Total hours
Reporting				
Standard Form and Content:				
96 122(c)				
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	1	8	480
96 133(a)	60	1	80	4800
Waivers:				
96.132(d)	60	1	16	960
96.134(b)	60	1	40	2400
96 135(d)	60	1	8	480
Total	60	1	530	**31,800

Section	Number of recordkeepers	Number hours per respondent	Total hours
Recordkeeping Burden			
96 129(a)(13)	60	16	960
Total	60	16	
Combined Burden—45 CFR 96			
		546	

For the purpose of calculating burden it has been assumed that all States could apply for each waiver.

The Department of Health and Human Services will submit a copy of this rule to OMB for its review of these information collection requirements. Organizations and individuals desiring to submit comments on the information collection requirements and the estimated burden should direct such comments to the agency official designated for this purpose whose name appears in this preamble and to SAMHSA Desk Officer Allison Eyd, Office of Information and Regulatory Affairs, OMB, New Executive Office

Building room 3001 725 17th St. NW Washington, DC 20503. It should be noted that the standard application form which is required to be used beginning fiscal year 1994, the annual report, and all other paperwork required under the rule will not be effective until approved by OMB pursuant to the Paperwork Reduction Act.

List of Subjects in 45 CFR Part 96

Alcohol abuse, Alcoholism, Drug abuse, Confidentiality, Health records.

For the reasons set out in the preamble, 45 CFR part 96 is amended as set forth below.

Dated March 10 1993

Approved March 24 1993
 Audrey F Manley
 Acting Assistant Secretary for Health
 Donna E. Shalala,
 Secretary

PART 96—BLOCK GRANTS

1 The authority citation for part 96 is revised to read as follows

Authority: 42 U.S.C. 300w et seq 42 U.S.C. 300x et seq 42 U.S.C. 300y et seq 42 U.S.C. 701 et seq 42 U.S.C. 8621 et seq 42 U.S.C. 9901 et seq 42 U.S.C. 1397 et seq 31 U.S.C. 1243 note unless otherwise noted.

2 Section 96 46 is revised to read as follows

§ 96.46 Substance abuse prevention and treatment services.

(a) This section applies to direct funding of Indian tribes and tribal organizations under the substance abuse prevention and treatment Block Grant

(b) For the purpose of determining eligible applicants under section 1933(d) of the Public Health Service Act (42 U.S.C. 300x-33(d)) an Indian tribe or tribal organization (as defined in subsections (b) and (c) of section 4 of the Indian Self Determination and Education Assistance Act) that received a direct grant under subpart I of part B of title XIX of the PHS Act (as such existed prior to October 1 1992) in fiscal year 1991 will be considered eligible for a grant under subpart 2 of part B of title XIX of the PHS Act.

(c) For purposes of the substance abuse prevention and treatment Block Grant, an Indian tribe or tribal organization is not required to comply with the following statutory provisions of the Public Health Service Act 1923 (42 U.S.C. 300x-23) 1925 (42 U.S.C. 300x-25) 1926 (42 U.S.C. 300x-26) 1928 (42 U.S.C. 300x-28) 1929 (42 U.S.C. 300x-29) and 1943(a)(1) (42 U.S.C. 300x-53(a)(1)) An Indian tribe or tribal organization is to comply with all other statutes and regulations applicable to the Substance Abuse Prevention and Treatment Block Grant. In each case in which an Indian Tribe receives a direct grant, the State is also responsible for providing services to Native Americans under the State's Block Grant program

3 Subpart L is revised to read as follows

Subpart L—Substance Abuse Prevention and Treatment Block Grant

- 96 120 Scope
- 96 121 Definitions
- 96 122 Application content and procedures
- 96 123 Assurances
- 96 124 Certain allocations
- 96 125 Primary prevention
- 96 126 Capacity of treatment for intravenous substance abusers

- 96 127 Requirements regarding tuberculosis
- 96 128 Requirements regarding human immunodeficiency virus
- 96 129 Revolving funds for establishment of homes in which recovering substance abusers may reside
- 96 131 Treatment services for pregnant women.
- 96 132 Additional agreements.
- 96 133 Submission to Secretary of Statewide assessment of needs.
- 96 134 Maintenance of effort regarding State expenditures.
- 96 135 Restrictions on expenditure of grant.
- 96 136 Independent peer review
- 96 137 Payment schedule

Subpart L—Substance Abuse Prevention and Treatment Block Grant

Authority: 42 U.S.C. 300x-21 to 300x-35 and 300x-51 to 300x-64.

§ 96 120 Scope.

This subpart applies to the Substance Abuse Prevention and Treatment Block Grant administered by the Substance Abuse and Mental Health Services Administration 45 C.F.R. Part 96 subparts A through F are applicable to this subpart to the extent that those subparts are consistent with subpart L. To the extent subparts A through F are inconsistent with subpart L the provisions of subpart L are applicable

§ 96 121 Definitions

Block Grant means the Substance Abuse Prevention and Treatment Block Grant, 42 U.S.C. 300x-21 et seq

Early Intervention Services Relating to HIV means

- (1) appropriate pretest counseling for HIV and AIDS
- (2) testing individuals with respect to such disease including tests to confirm the presence of the disease tests to diagnose the extent of the deficiency in the immune system and tests to provide information on appropriate therapeutic measures for preventing and treating the deterioration of the immune system and for preventing and treating conditions arising from the disease
- (3) appropriate post test counseling and
- (4) providing the therapeutic measures described in Paragraph (2) of this definition

Fiscal Year unless provided otherwise means the Federal fiscal year

Interim Services or Interim Substance Abuse Services means services that are provided until an individual is admitted to a substance abuse treatment program. The purposes of the services are to reduce the adverse health effects of such abuse promote the health of the individual and reduce the risk of transmission of disease. At a minimum interim services include counseling and

education about HIV and tuberculosis (TB) about the risks of needle-sharing the risks of transmission to sexual partners and infants and about steps that can be taken to ensure that HIV and TB transmission does not occur as well as referral for HIV or TB treatment services if necessary. For pregnant women interim services also include counseling on the effects of alcohol and drug use on the fetus as well as referral for prenatal care

Primary Prevention Programs are those directed at individuals who have not been determined to require treatment for substance abuse. Such programs are aimed at educating and counseling individuals on such abuse and providing for activities to reduce the risk of such abuse

Principal Agency is the single State agency responsible for planning carrying out and evaluating activities to prevent and treat substance abuse and related activities

Rural Area The definition of a rural area within a State shall be the latest definition of the Bureau of the Census Department of Commerce

Secretary is the Secretary of the United States Department of Health and Human Services or the Secretary's designee

State unless provided otherwise includes the 50 States the District of Columbia, the Commonwealth of Puerto Rico the U.S. Virgin Islands Guam America Samoa the Commonwealth of the Northern Mariana Islands Palau, Micronesia and the Marshall Islands.

State Medical Director for Substance Abuse Services is a licensed physician with the knowledge skill and ability to address the multiple physical and psychological problems associated with substance abuse and who provides the principle agency with clinical consultation and direction regarding effective substance abuse treatment, effective primary medical care effective infection control and public health and quality assurance.

Substance Abuse is defined to include the abuse or illicit use of alcohol or other drugs

Tuberculosis Services means

- (1) Counseling the individual with respect to tuberculosis
- (2) Testing to determine whether the individual has been infected with mycobacteria tuberculosis to determine the appropriate form of treatment for the individual and
- (3) Providing for or referring the individuals infected by mycobacteria tuberculosis for appropriate medical evaluation and treatment.

§ 96.122 Application content and procedures

(a) For each fiscal year beginning with fiscal year 1993 the State shall submit an application to such address as the Secretary determines is appropriate

(b) For fiscal year 1993 applicants must submit an application containing information which conforms to the assurances listed under § 96.123 the report as provided in § 96.122(f) and the State plan as provided in § 96.122(g)

(c) Beginning fiscal year 1994 applicants shall only use standard application forms prescribed by the granting agency with the approval of the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 Applicants must follow all applicable instructions that bear OMB clearance numbers The application will require the State to submit the assurances listed under § 96.123 the report as provided in § 96.122(f) and the State Plan as provided in § 96.122(g)

(d) The application (in substantial compliance with the statutory and regulatory provisions for the Block Grant) shall be submitted for fiscal year 1993 no later than ninety days after publication of these regulations and for subsequent years no later than March 31 of the fiscal year for which the State is applying

(e) The funding agreements and assurances in the application shall be made through certification by the State's chief executive officer personally or by an individual authorized to make such certification on behalf of the chief executive officer When a delegation has occurred a copy of the current delegation of authority must be submitted with the application

(f) A report shall be submitted annually with the application and State Plan Among other things the report must contain information as determined by the Secretary to be necessary to determine the purposes and the activities of the State for which the Block Grant was expended. The report shall include (but is not limited to) the following

(1) For the fiscal year three years prior to the fiscal year for which the State is applying for funds

(i) A statement of whether the State exercised its discretion under applicable law to transfer Block Grant funds from substance abuse services to mental health services or vice versa and a description of the transfers which were made

(ii) A description of the progress made by the State in meeting the prevention and treatment goals objectives and

activities submitted in the application for the relevant year

(iii) A description of the amounts expended under the Block Grant by the State agency by activity

(iv) A description of the amounts expended on primary prevention and early intervention activities (if reporting on fiscal years 1990, 1991 and 1992 only) and for primary prevention activities (if reporting on fiscal years 1993 and subsequent years)

(v) A description of the amounts expended for activities relating to substance abuse such as planning coordination needs assessment, quality assurance training of counselors program development, research and development and the development of information systems

(vi) A description of the entities their location and the total amount the entity received from Block Grant funds with a description of the activities undertaken by the entity

(vii) A description of the use of the State's revolving funds for establishment of group homes for recovering substance abusers as provided by § 96.129 including the amount available in the fund throughout the fiscal year and the number and amount of loans made that fiscal year

(viii) A detailed description of the State's programs for women and, in particular for pregnant women and women with dependent children, if reporting on fiscal years 1990 1991, or 1992 and pregnant women or women with dependent children for fiscal year 1993 and subsequent fiscal years

(ix) A detailed description of the State's programs for intravenous drug users and

(x) For applications for fiscal year 1996 and subsequent fiscal years a description of the State's expenditures for tuberculosis services and if a designated State early intervention services for HIV

(2) For the most recent 12 month State expenditure period for which expenditure information is complete

(i) A description of the amounts expended by the principal agency for substance abuse prevention and treatment activities by activity and source of funds

(ii) A description of substance abuse funding by other State agencies and offices by activity and source of funds when available, and

(iii) A description of the types and amounts of substance abuse services purchased by the principal agency

(3) For the fiscal year two years prior to the fiscal year for which the State is applying for funds

(i) A description of the amounts obligated under the Block Grant by the principal agency by activity,

(ii) A description of the amounts obligated for primary prevention and early intervention (if reporting on fiscal years 1990 1991 and 1992 activities only) and primary prevention activities (if reporting on fiscal years 1993 and subsequent year activities)

(iii) A description of the entities to which Block Grant funds were obligated

(iv) A description of the State's policies procedures and laws regarding substance abuse prevention especially the use of alcohol and tobacco products by minors

(v) For applications for fiscal year 1995 and all subsequent fiscal years a description of the State's procedures and activities undertaken to comply with the requirement to conduct independent peer review as provided by § 96.136

(vi) For applications for fiscal year 1995 and all subsequent fiscal years a description of the State's procedures and activities undertaken to comply with the requirement to develop capacity management and waiting list systems as provided by §§ 96.126 and 96.131 as well as an evaluation summary of these activities and

(vii) For applications for fiscal year 1995 and subsequent fiscal years a description of the strategies used for monitoring program compliance with § 96.126(f) § 96.127(b) and § 96.131(f) as well as a description of the problems identified and the corrective actions taken

(4) The aggregate State expenditures by the principal agency for authorized activities for the two State fiscal years preceding the fiscal year for which the State is applying for a grant pursuant to § 96.134(d)

(5) For the previous fiscal year

(i) A description of the State's progress in meeting the goals objectives and activities included in the previous year's application, and a brief description of the recipients of the Block Grant funds

(ii) A description of the methods used to calculate the following

(A) The base for services to pregnant women and women with dependent children as required by § 96.124,

(B) The base for tuberculosis services as required by § 96.127 and

(C) For designated States the base for HIV early intervention services as required by § 96.128

(iii) For applications for fiscal years 1994 and 1995 only a description of the State's progress in the development of protocols for and the implementation of

tuberculosis services and if a designated State early intervention services for HIV and

(iv) For applications for fiscal year 1994 only a description of the States progress in the development, implementation and utilization of capacity management and waiting list systems

(6) [Reserved]

(7) In addition to the information above any information that the Secretary may from time to time require consistent with the Paperwork Reduction Act.

(g) For each fiscal year beginning fiscal year 1993 the State Plan shall be submitted to the Secretary and shall include the following

(1) For fiscal years 1993 and 1994 a statement on whether the Governor intends to exercise discretion under applicable law to transfer Block Grant funds from the Substance Abuse Prevention and Treatment Block Grant allotment under section 1921 of the PHS Act to the Community Mental Health Services Block Grant allotment under section 1911 of the PHS Act or vice versa and a description of the planned transfer

(2) A budget of expenditures which provides an estimate of the use and distribution of Block Grant and other funds to be spent by the agency administering the Block Grant during the period covered by the application by activity and source of funds

(3) A description of how the State carries out planning including how the State identifies substatg areas with the greatest need, what process the State uses to facilitate public comment on the plan and what criteria the State uses in deciding how to allocate Block Grant funds

(4) A detailed description of the State procedures to monitor programs that reach 90% capacity pursuant to § 96 126(a)

(5) A detailed description of the State procedures to implement the 14/120 day requirement provided by § 96 126(b) as well as the interim services to be provided and a description of the strategies to be used in monitoring program compliance in accordance with § 96 126(f)

(6) A full description of the outreach efforts States will require entities which receive funds to provide pursuant to § 96 126(e)

(7) A detailed description of the State procedures implementing TB services pursuant to § 96 127 and a description of the strategies to be used in monitoring program compliance in accordance with § 96 127(b)

(8) A detailed description of the State s procedures implementing HIV services pursuant to § 96 128 if considered a designated State

(9) A description of estimates of non Federal dollars to be spent for early intervention services relating to HIV if a designated State and tuberculosis services for the fiscal year covered by the application as well as the amounts actually spent for such services for the two previous fiscal years

(10) For fiscal year 1993 a detailed description of the State s revolving fund for establishment of group homes for recovering substance abusers pursuant to § 96 129 and, for subsequent years any revisions to the program,

(11) A detailed description of State procedures implementing § 96 131 relating to treatment services for pregnant women

(12) Unless waived a description on how the State will improve the process for referrals for treatment will ensure that continuing education is provided and will coordinate various activities and services as provided by § 96 132

(13) Statewide assessment of needs as provided in § 96 133

(14) The aggregate State dollar projected expenditures by the principal agency of a State for authorized activities for the fiscal year for which the Block Grant is to be expended as well as the aggregate obligations or expenditures when available for authorized activities for the two years prior to such fiscal year as required by § 96 134

(15) Unless waived a description of the services and activities to be provided by the State with Block Grant funds consistent with § 96 124 for allocations to be spent on services to pregnant women and women with dependent children alcohol and other drug treatment and prevention including primary prevention and any other requirement

(16) A description of the State procedures to implement § 96 132(e) regarding inappropriate disclosure of patient records

(17) A description of the amounts to be spent for primary prevention in accordance with § 96 125

(18) A description of the amounts to be spent on activities relating to substance abuse such as planning coordination needs assessment, quality assurance training of counselors program development, research and development and the development of information systems

(19) A description of the State plans regarding purchasing substance abuse services

(20) A description of how the State intends to monitor and evaluate the performance of substance abuse service providers in accordance with § 96.136

(21) A description of the State s overall goals for Block Grant expenditures specific objectives under each goal, and the activities the State will carry out to achieve these objectives and

(22) Such other information as the Secretary may from time to time require consistent with the Paperwork Reduction Act.

(h) The Secretary will approve an application which includes the assurances the State plan and the report that satisfies the requirements of this part and the relevant sections of the PHS Act As indicated above the State is required to provide descriptions of the State s procedures to implement the provisions of the Act and the regulations Unless provided otherwise by these regulations the Secretary will approve procedures which are provided as examples in the regulations or the State may submit other procedures which the Secretary determines to reasonably implement the requirements of the Act

§ 96 123 Assurances

(a) The application must include assurances that

(1) the State will expend the Block Grant in accordance with the percentage to be allocated to treatment, prevention and other activities as prescribed by law and also for the purposes prescribed by law

(2) The activities relating to intravenous drug use pursuant to § 96 126 will be carried out

(3) The TB services and referral will be carried out pursuant to § 96 127 as well as the early intervention services for HIV provided for in § 96 128 if a designated State

(4) The revolving funds to establish group homes for recovering substance abusers is in place consistent with the provisions of § 96 129 and the loans will be made and used as provided for by law

(5) [Reserved]

(6) Pregnant women are provided preference in admission to treatment centers as provided by § 96 131 and are provided interim services as necessary and as required by law

(7) The State will improve the process in the State for referrals of individuals to the treatment modality that is most appropriate for the individuals will ensure that continuing education is provided to employees of any funded entity providing prevention activities or treatment services and will coordinate

prevention activities and treatment services with the provision of other appropriate services as provided by § 96 132

(8) The State will submit an assessment of need as required by section 96 133

(9) The State will for such year maintain aggregate State expenditures by the principal agency of a State for authorized activities at a level that is not less than the average level of such expenditures maintained by the State for the 2 year period preceding the fiscal year for which the State is applying for the grant as provided by § 96 134

(10) The Block Grant will not be used to supplant State funding of alcohol and other drug prevention and treatment programs

(11) For purposes of maintenance of effort pursuant to §§ 96 127(f) 96 128(f) and 96 134 the State will calculate the base using Generally Accepted Accounting Principles and the composition of the base will be applied consistently from year to year

(12) The State will for the fiscal year for which the grant is provided comply with the restrictions on the expenditure of Block Grant funds as provided by § 96 135

(13) The State will make the State Plan public within the State in such manner as to facilitate comment from any person (including any Federal or other public agency) during the development of the State Plan and after the submission of the State Plan (including any revisions) to the Secretary as provided by § 1941 of the PHS Act

(14) The State will for the fiscal year for which the grant is provided provide for independent peer review to assess the quality appropriateness and efficacy of treatment services provided in the State to individuals under the program involved as required by § 96 136

(15) The State has in effect a system to protect from inappropriate disclosure patient records maintained by the State in connection with an entity which is receiving amounts from the grant

(16) The State will comply with chapter 75 of title 31 United States Code pertaining to audits and

(17) The State will abide by all applicable Federal laws and regulations including those relating to lobbying (45 CFR Part 93) drug free workplace (45 CFR 76 600) discrimination (PHS Act Sec. 1947) false statements or failure to disclose certain events (PHS Act Sec. 1946) and as to the State of Hawaii services for Native Hawaiians (PHS Act Sec 1953)

§ 96 124 Certain allocations.

(a) States are required to expend the Block Grant on various activities in certain proportions. Specifically as to treatment and prevention the State shall expend the grant as follows

(1) not less than 35 percent for prevention and treatment activities regarding alcohol, and

(2) not less than 35 percent for prevention and treatment activities regarding other drugs

(b) The States are also to expend the Block Grant on primary prevention programs as follows

(1) Consistent with § 96 125 the State shall expend not less than 20 percent for programs for individuals who do not require treatment for substance abuse which programs—

(i) educate and counsel the individuals on such abuse and (ii) provide for activities to reduce the risk of such abuse by the individuals

(2) The State shall in carrying out paragraph (b)(1) of this section—

(i) give priority to programs for populations that are at risk of developing a pattern of such abuse and

(ii) ensure that programs receiving priority under paragraph (b)(2)(i) of this section develop community based strategies for prevention of such abuse including strategies to discourage the use of alcoholic beverages and tobacco products by individuals to whom it is unlawful to sell or distribute such beverages or products

(c) Subject to paragraph (d) of this section a State is required to expend the Block Grant on women services as follows

(1) The State for fiscal year 1993 shall expend not less than five percent of the grant to increase (relative to fiscal year 1992) the availability of treatment services designed for pregnant women and women with dependent children (either by establishing new programs or expanding the capacity of existing programs) The base for fiscal year 1993 shall be an amount equal to the fiscal year 1992 alcohol and drug services Block Grant expenditures and State expenditures for pregnant women and women with dependent children as described in paragraph (e) of this section and to this base shall be added at least 5 percent of the 1993 Block Grant allotment. The base shall be calculated using Generally Accepted Accounting Principles and the composition of the base shall be applied consistently from year to year States shall report the methods used to calculate their base for fiscal year 1992 expenditures on treatment for pregnant women and women with dependent children

(2) For fiscal year 1994 the State shall consistent with paragraph (c)(1) of this section, expend not less than five percent of the grant to increase (relative to fiscal year 1993) the availability of such services to pregnant women and women with dependent children.

(3) For grants beyond fiscal year 1994 the States shall expend no less than an amount equal to the amount expended by the State for fiscal year 1994

(d) Upon the request of a State the Secretary may waive all or part of the requirement in paragraph (c) of this section if the Secretary determines that the State is providing an adequate level of services for this population. In determining whether an adequate level of services is being provided the Secretary will review the extent to which such individuals are receiving services. This determination may be supported by a combination of criminal justice data the National Drug and Treatment Units Survey statewide needs assessment data waiting list data welfare department data including medicaid expenditures, or other State statistical data that are systematically collected. The Secretary will also consider the extent to which the State offers the minimum services required under § 96 124(e). The Secretary shall approve or deny a request for a waiver not later than 120 days after the date on which the request is made. Any waiver provided by the Secretary shall be applicable only to the fiscal year involved

(e) With respect to paragraph (c) of this section the amount set aside for such services shall be expended on individuals who have no other financial means of obtaining such services as provided in § 96 137. All programs providing such services will treat the family as a unit and therefore will admit both women and their children into treatment services if appropriate. The State shall ensure that at a minimum treatment programs receiving funding for such services also provide or arrange for the provision of the following services to pregnant women and women with dependent children, including women who are attempting to regain custody of their children

(1) primary medical care for women including referral for prenatal care and while the women are receiving such services child care

(2) primary pediatric care, including immunization for their children

(3) gender specific substance abuse treatment and other therapeutic interventions for women which may address issues of relationships sexual and physical abuse and parenting and

id care while the women are receiving these services

4) therapeutic interventions for children in custody of women in treatment which may among other things address their developmental needs their issues of sexual and physical abuse and neglect; and

(5) sufficient case management and transportation to ensure that women and their children have access to services provided by paragraphs (e) (1) through (4) of this section

(f) Procedures for the implementation of paragraphs (c) and (e) of this section will be developed in consultation with the State Medical Director for Substance Abuse Services.

§ 96.125 Primary prevention.

(a) For purposes of § 96.124 each State/Territory shall develop and implement a comprehensive prevention program which includes a broad array of prevention strategies directed at individuals not identified to be in need of treatment. The comprehensive program shall be provided either directly or through one or more public or nonprofit private entities. The comprehensive primary prevention program shall include activities and services provided in a variety of settings for both the general population as well as targeting sub-groups who are at high risk for substance abuse.

(b) In implementing the prevention program the State shall use a variety of strategies as appropriate for each target group including but not limited to the following:

(1) *Information Dissemination* This strategy provides awareness and knowledge of the nature and extent of alcohol tobacco and drug use abuse and addiction and their effects on individuals families and communities. It also provides knowledge and awareness of available prevention programs and services. Information dissemination is characterized by one way communication from the source to the audience with limited contact between the two. Examples of activities conducted and methods used for this strategy include (but are not limited to) the following:

- (i) Clearinghouse/information resource center(s)
- (ii) Resource directories
- (iii) Media campaigns
- (iv) Brochures
- (v) Radio/TV public service announcements
 - 1) Speaking engagements
 - ii) Health fairs/health promotion and information fairs

(2) *Education* This strategy involves two-way communication and is

distinguished from the Information Dissemination strategy by the fact that interaction between the educator/facilitator and the participants is the basis of its activities. Activities under this strategy aim to affect critical life and social skills including decision making refusal skills critical analysis (e.g. of media messages) and systematic judgment abilities. Examples of activities conducted and methods used for this strategy include (but are not limited to) the following:

- (i) Classroom and/or small group sessions (all ages)
- (ii) Parenting and family management classes
- (iii) Peer leader/helper programs.
- (iv) Education programs for youth groups and
- (v) Children of substance abusers groups

(3) *Alternatives* This strategy provides for the participation of target populations in activities that exclude alcohol tobacco and other drug use. The assumption is that constructive and healthy activities offset the attraction to or otherwise meet the needs usually filled by alcohol tobacco and other drugs and would therefore minimize or obviate resort to the latter. Examples of activities conducted and methods used for this strategy include (but are not limited to) the following:

- (i) Drug free dances and parties,
- (ii) Youth/adult leadership activities
- (iii) Community drop in centers and
- (iv) Community service activities

(4) *Problem Identification and Referral* This strategy aims at identification of those who have indulged in illegal/age-inappropriate use of tobacco or alcohol and those individuals who have indulged in the first use of illicit drugs in order to assess if their behavior can be reversed through education. It should be noted, however that this strategy does not include any activity designed to determine if a person is in need of treatment. Examples of activities conducted and methods used for this strategy include (but are not limited to) the following:

- (i) Employee assistance programs
- (ii) Student assistance programs and
- (iii) Driving while under the influence/driving while intoxicated education programs

(5) *Community Based Process* This strategy aims to enhance the ability of the community to more effectively provide prevention and treatment services for alcohol tobacco and drug abuse disorders. Activities in this strategy include organizing planning enhancing efficiency and effectiveness

of services implementation inter agency collaboration coalition building and networking. Examples of activities conducted and methods used for this strategy include (but are not limited to) the following:

- (i) Community and volunteer training e.g. neighborhood action training training of key people in the system staff/officials training.
- (ii) Systematic planning
- (iii) Multi-agency coordination and-collaboration
- (iv) Accessing services and funding and
- (v) Community team-building

(6) *Environmental* This strategy establishes or changes written and unwritten community standards, codes and attitudes, thereby influencing incidence and prevalence of the abuse of alcohol, tobacco and other drugs used in the general population. This strategy is divided into two subcategories to permit distinction between activities which center on legal and regulatory initiatives and those which relate to the service and action-oriented initiatives. Examples of activities conducted and methods used for this strategy shall include (but not be limited to) the following:

- (i) promoting the establishment and review of alcohol, tobacco and drug use policies in schools,
- (ii) technical assistance to communities to maximize local enforcement procedures governing availability and distribution of alcohol, tobacco and other drug use
- (iii) modifying alcohol and tobacco advertising practices and
- (iv) product pricing strategies

§ 96.126 Capacity of treatment for intravenous substance abusers.

(a) In order to obtain Block Grant funds the State must require programs that receive funding under the grant and that treat individuals for intravenous substance abuse to provide to the State upon reaching 90 percent of its capacity to admit individuals to the program a notification of that fact within seven days. In carrying out this section the State shall establish a capacity management program which reasonably implements this section—that is, which enables any such program to readily report to the State when it reaches 90 percent of its capacity—and which ensures the maintenance of a continually updated record of all such reports and which makes access to such capacity information available to such programs.

(b) In order to obtain Block Grant funds the State shall ensure that each individual who requests and is in need

of treatment for intravenous drug abuse is admitted to a program of such treatment not later than—

- (1) 14 days after making the request for admission to such a program or
- (2) 120 days after the date of such request, if no such program has the capacity to admit the individual on the date of such request and if interim services including referral for prenatal care are made available to the individual not later than 48 hours after such request.

(c) In carrying out subsection (b) the State shall establish a waiting list management program which provides systematic reporting of treatment demand. The State shall require that any program receiving funding from the grant, for the purposes of treating injecting drug abusers establish a waiting list that includes a unique patient identifier for each injecting drug abuser seeking treatment including those receiving interim services while awaiting admission to such treatment. For individuals who cannot be placed in comprehensive treatment within 14 days the State shall ensure that the program provide such individuals interim services as defined in § 96 121 and ensure that the programs develop a mechanism for maintaining contact with the individuals awaiting admission. The States shall also ensure that the programs consult the capacity management system as provided in paragraph (a) of this section so that patients on waiting lists are admitted at the earliest possible time to a program providing such treatment within reasonable geographic area.

(d) In carrying out paragraph (b)(2) of this section the State shall ensure that all individuals who request treatment and who can not be placed in comprehensive treatment within 14 days are enrolled in interim services and those who remain active on a waiting list in accordance with paragraph (c) of this section are admitted to a treatment program within 120 days. If a person cannot be located for admission into treatment or if a person refuses treatment, such persons may be taken off the waiting list and need not be provided treatment within 120 days. For example if such persons request treatment later and space is not available they are to be provided interim services placed on a waiting list and admitted to a treatment program within 120 days from the latter request

(e) The State shall require that any entity that receives funding for treatment services for intravenous drug abuse carry out activities to encourage individuals in need of such treatment to undergo such treatment. The States

shall require such entities to use outreach models that are scientifically sound or if no such models are available which are applicable to the local situation to use an approach which reasonably can be expected to be an effective outreach method. The model shall require that outreach efforts include the following

- (1) Selecting training and supervising outreach workers
- (2) Contacting, communicating and following-up with high risk substance abusers their associates, and neighborhood residents within the constraints of Federal and State confidentiality requirements including 42 C.F.R. Part 2
- (3) Promoting awareness among injecting drug abusers about the relationship between injecting drug abuse and communicable diseases such as HIV
- (4) Recommend steps that can be taken to ensure that HIV transmission does not occur and
- (5) Encouraging entry into treatment.

(f) The State shall develop effective strategies for monitoring programs compliance with this section. States shall report under the requirements of § 96 122(g) on the specific strategies to be used to identify compliance problems and corrective actions to be taken to address those problems

§ 96 127 Requirements regarding tuberculosis.

(a) States shall require any entity receiving amounts from the grant for operating a program of treatment for substance abuse to follow procedures developed by the principal agency of a State for substance abuse in consultation with the State Medical Director for Substance Abuse Services and in cooperation with the State Department of Health/Tuberculosis Control Officer which address how the program—

(1) Will directly or through arrangements with other public or nonprofit private entities routinely make available tuberculosis services as defined in § 96 121 to each individual receiving treatment for such abuse

(2) In the case of an individual in need of such treatment who is denied admission to the program on the basis of the lack of the capacity of the program to admit the individual will refer the individual to another provider of tuberculosis services and

(3) Will implement infection control procedures established by the principal agency of a State for substance abuse in cooperation with the State Department of Health/Tuberculosis Control Officer which are designed to prevent the

transmission of tuberculosis including the following

- (i) Screening of patients
- (ii) Identification of those individuals who are at high risk of becoming infected and
- (iii) Meeting all State reporting requirements while adhering to Federal and State confidentiality requirements including 42 CFR part 2 and

(4) will conduct case management activities to ensure that individuals receive such services

(b) The State shall develop effective strategies for monitoring programs compliance with this section. States shall report under the requirements of § 96 122(g) on the specific strategies to be used to identify compliance problems and corrective actions to be taken to address those problems. The principal agency in cooperation with the State Department of Health/Tuberculosis Control Officer shall also establish linkages with other health care providers to ensure that tuberculosis services are routinely made available. All individuals identified with active tuberculosis shall be reported to the appropriate State official as required by law and consistent with paragraph (a)(3)(iii) of this section

(c) With respect to services provided for by a State for purposes of compliance with this section the State shall maintain Statewide expenditures of non Federal amounts for such services at a level that is not less than an average level of such expenditures maintained by the State for the 2 year period preceding the first fiscal year for which the State receives such a grant. In making this determination States shall establish a reasonable funding base for fiscal year 1993. The base shall be calculated using Generally Accepted Accounting Principles and the composition of the base shall be applied consistently from year to year

§ 96 128 Requirements regarding human immunodeficiency virus

(a) In the case of a designated State as described in paragraph (b) of this section the State shall do the following—

(1) with respect to individuals undergoing treatment for substance abuse the State shall subject to paragraph (c) of this section carry out one or more projects to make available to the individuals early intervention services for HIV disease as defined in § 96 121 at the sites at which the individuals are undergoing such treatment

(2) for the purpose of providing such early intervention services through such

cts the State shall make available the grant the amounts prescribed action 1924 of the PHS Act,

(3) the State shall subject to paragraph (d) of this section carry out such projects only in geographic areas of the State that have the greatest need for the projects

(4) the State shall require programs participating in the project to establish linkages with a comprehensive community resource network of related health and social services organizations to ensure a wide-based knowledge of the availability of these services and

(5) the State shall require any entity receiving amounts from the Block Grant for operating a substance abuse treatment program to follow procedures developed by the principal agency of a State for substance abuse, in consultation with the State Medical Director for Substance Abuse Services and in cooperation with the State Department of Health/Communicable Disease Officer

(b) For purposes of this section a designated State is any State whose rate of cases of acquired immune deficiency syndrome is 10 or more such cases per 100 000 individuals (as indicated by the number of such cases reported and confirmed by the director of the Centers for Disease Control for the most recent calendar year for which the data are available)

(c) With respect to programs that provide treatment services for substance abuse the State shall ensure that each such program participating in a project under paragraph (a) of this section will be a program that began operation prior to the fiscal year for which the State is applying to receive the grant. A program that so began operation may participate in a project under paragraph (a) of this section without regard to whether the program has been providing early intervention services for HIV disease

(d) If the State plans to carry out 2 or more projects under paragraph (a) of this section the State shall carry out one such project in a rural area of the State unless the requirement is waived. The Secretary shall waive the requirement if the State certifies to the Secretary that

(1) The rate of cases of acquired immune deficiency syndrome is less than or equal to two such cases per 100 000 individuals in any rural area of the State or there are so few infected persons that establishing a project in the area is not reasonable or

(2) There are no rural areas in the State as defined in § 96 121

(f) With respect to the provision of early intervention services for HIV disease to an individual the State shall ensure that the entities comply with

§ 96 137 regarding payment and § 96 135 regarding restrictions on expenditure of grant. The State shall also ensure that such services will be undertaken voluntarily by and with the informed consent of, the individual and undergoing such services will not be required as a condition of receiving treatment services for substance abuse or any other services

(f) With respect to services provided for a State for purposes of compliance with this section the State shall maintain Statewide expenditures of non Federal amounts for such services at a level that is not less than the average level of such expenditures maintained by the State for 2 year period preceding the first fiscal year for which the State receives such a grant. In making this determination States shall establish a reasonable base for fiscal year 1993. The base shall be calculated using Generally Accepted Accounting Principles and the composition of the base shall be applied consistently from year to year

§ 96 129 Revolving funds for establishment of homes in which recovering substance abusers may reside.

(a) The State shall establish and provide for the ongoing operation of a revolving fund as follows:

(1) The purpose of the fund is to make loans for the costs of establishing programs for the provision of housing in which individuals recovering from alcohol and drug abuse may reside in groups of not less than six individuals;

(2) Not less than \$100 000 will be available for the revolving fund

(3) Loans made from the revolving fund do not exceed \$4 000 and that each such loan is repaid to the revolving fund not later than 2 years after the date on which the loan is made

(4) Each such loan is repaid by such residents through monthly installments by the date specified in the loan agreement involved

(5) Such loans are made only to nonprofit private entities agreeing that in the operation of the program established pursuant to the loan—

(i) The use of alcohol or any illegal drug in the housing provided by the program will be prohibited

(ii) Any resident of the housing who violates such prohibition will be expelled from the housing

(iii) The costs of the housing including fees for rent and utilities will be paid by the residents of the housing and

(iv) The residents of the housing will through a majority vote of the residents otherwise establish policies governing residence in the housing including the

manner in which applications for residence in the housing are approved

(6) States shall identify and clearly define legitimate purposes for which the funds will be spent, such as first month's rent, necessary furniture (e.g., beds), facility modifications (e.g., conversion of basement into a game room or extra bedrooms), and purchase of amenities which foster healthy group living (e.g., dishwasher)

(7) In managing the revolving fund the State and the financial entity managing the fund for the State shall abide by all Federal, State and local laws and regulations

(8) If the State decides to indirectly manage the fund using a private nonprofit entity as the fund management group the State shall establish reasonable criteria for selecting the group such as qualifications, expertise, experience and capabilities of the group and the State shall require that these entities abide by all Federal, State and local laws and regulations;

(9) The State may seek assistance to approve or deny applications from entities that meet State-established criteria

(10) The State shall set reasonable criteria in determining the eligibility of prospective borrowers such as qualifications, expertise, capabilities, the acceptability of a proposed plan to use the funds and operate the house and an assessment of the potential borrower's ability to pay back the funds

(11) The State shall establish a procedure and process for applying for a loan under the program which may include completion of the application, personal interviews and submission of evidence to support eligibility requirements as well as establish a written procedure for repayment which will set forth reasonable penalties for late or missed payments and liability and recourse for default

(12) The State shall provide clearly defined written instructions to applicants which lays out: timeliness, milestones, required documentation, notification of reasonable penalties for late or missed payments and recourse for default, notification on legitimate purposes for which the loan may be spent and other procedures required by the State and

(13) The State shall keep a written record of the number of loans and amount of loans provided, the identities of borrowers and the repayment history of each borrower and return it for three years

(b) The requirements established in paragraph (a) of this section shall not apply to any territory of the United

States other than the Commonwealth of Puerto Rico

§ 96 131 Treatment services for pregnant women.

(a) The State is required to in accordance with this section ensure that each pregnant woman in the State who seeks or is referred for and would benefit from such services is given preference in admissions to treatment facilities receiving funds pursuant to the grant. In carrying out this section the State shall require all entities that serve women and who receive such funds to provide preference to pregnant women Programs which serve an injecting drug abuse population and who receive Block Grant funds shall give preference to treatment as follows

- (1) Pregnant injecting drug users
- (2) Pregnant substance abusers
- (3) Injecting drug users and
- (4) All others

(b) The State will in carrying out this provision publicize the availability to such women of services from the facilities and the fact that pregnant women receive such preference This may be done by means of street outreach programs ongoing public service announcements (radio/television) regular advertisements in local/regional print media posters placed in targeted areas and frequent notification of availability of such treatment distributed to the network of community based organizations health care providers and social service agencies

(c) The State shall in carrying out paragraph (a) of this section require that in the event that a treatment facility has insufficient capacity to provide treatment services to any such pregnant woman who seeks the services from the facility the facility refer the woman to the State This may be accomplished by establishing a capacity management program utilizing a toll free number an automated reporting system and/or other mechanisms to ensure that pregnant women in need of such services are referred as appropriate The State shall maintain a continually updated system to identify treatment capacity for any such pregnant women and will establish a mechanism for matching the women in need of such services with a treatment facility that has the capacity to treat the woman

(d) The State in the case of each pregnant woman for whom a referral under paragraph (a) of this section is made to the State—

(1) will refer the woman to a treatment facility that has the capacity to provide treatment services to the woman or

(2) will if no treatment facility has the capacity to admit the woman make available interim services including a referral for prenatal care available to the woman not later than 48 hours after the woman seeks the treatment services

(e) Procedures for the implementation of this section shall be developed in consultation with the State Medical Director for Substance Abuse Services

(f) The State shall develop effective strategies for monitoring programs compliance with this section States shall report under the requirements of § 96 122(g) on the specific strategies to be used to identify compliance problems and corrective actions to be taken to address those problems

§ 96 132 Additional agreements.

(a) With respect to individuals seeking treatment services the State is required to improve (relative to fiscal year 1992) the process in the State for referring the individuals to treatment facilities that can provide to the individuals the treatment modality that is most appropriate for the individuals Examples of how this may be accomplished include the development and implementation of a capacity management/waiting list management system the utilization of a toll free number for programs to report available capacity and waiting list data and the utilization of standardized assessment procedures that facilitate the referral process

(b) With respect to any facility for treatment services or prevention activities that is receiving amounts from a Block Grant continuing education in such services or activities (or both as the case may be) shall be made available to employees of the facility who provide the services or activities The States will ensure that such programs include a provision for continuing education for employees of the facility in its funding agreement

(c) The State shall coordinate prevention and treatment activities with the provision of other appropriate services (including health social correctional and criminal justice educational vocational rehabilitation and employment services) In evaluating compliance with this section the Secretary will consider such factors as the existence of memoranda of understanding between various service providers/agencies and evidence that the State has included prevention and treatment services coordination in its grants and contracts

(d) Upon the request of a State the Secretary may provide to a State a waiver of any or all of the requirements established in paragraphs (a) (b) and (c)

of this section if the Secretary determines that, with respect to services for the prevention and treatment of substance abuse the requirement involved is unnecessary for maintaining quality in the provision of such services in the State In evaluating whether to grant or deny a waiver the Secretary will rely on information drawn from the independent peer review/quality assurance activities conducted by the State For example a State may be eligible for a waiver of the requirement of paragraph (a) of this section if a State already has a well developed process for referring individuals to treatment facilities that can provide to the individuals the treatment modality that is most appropriate for the individuals The Secretary will approve or deny a request for a waiver not later than 120 days after the date on which the request is made Any waiver provided by the Secretary for paragraphs (a) (b) and (c) of this section will be applicable only to the fiscal year involved

(e) The State is also required to have in effect a system to protect from inappropriate disclosure patient records maintained by the State in connection with an activity funded under the program involved or by any entity which is receiving amounts from the grant and such system shall be in compliance with all applicable State and Federal laws and regulations including 42 CFR part 2 This system shall include provisions for employee education on the confidentiality requirements and the fact that disciplinary action may occur upon inappropriate disclosures This requirement cannot be waived

§ 96 133 Submission to Secretary of Statewide assessment of needs

(a) The State is required to submit to the Secretary an assessment of the need in the State for authorized activities both by locality and by the State in general The State is to provide a broad range of information which includes the following

(1) The State is to submit data which shows the incidence and prevalence in the State of drug abuse and the incidence and prevalence in the State of alcohol abuse and alcoholism For fiscal years 1993 through 1996 the State shall submit its best available data on the incidence and prevalence of drug and alcohol abuse and alcoholism The State shall also provide a summary describing the weakness and bias in the data and a description on how the State plans to strengthen the data in the future

(2) The State shall provide a description on current substance abuse prevention and treatment activities

For fiscal year 1993 the State shall use its best available data on current prevention and treatment activities in the State in such detail as it finds reasonably practicable given its own data collection activities and records.

(ii) For fiscal year 1994 and subsequent years the State shall provide a detailed description on current prevention and treatment activities in the State. This report shall include a detailed description of the intended use of the funds relating to prevention and treatment as well as a description of treatment capacity. As to primary prevention activities the activities must be broken down by strategies used such as those provided in section 96 125 including the specific activities conducted. The State shall provide the following data if available: the specific risk factors being addressed by activity; the age, race/ethnicity and gender of the population being targeted by the prevention activity; and the community size and type where the activity is carried out. As to all treatment and prevention activities including primary prevention the State shall provide the identities of the entities that provide the services and describe the services provided. The State shall submit information on treatment utilization to describe the type of care and the utilization according to primary diagnosis of alcohol or drug abuse or a dual diagnosis of drug and alcohol abuse.

(3) The State may describe the need for technical assistance to carry out Block Grant activities including activities relating to the collection of incidence and prevalence data identified in paragraph (a)(1) of this section.

(4) The State shall establish goals and objectives for improving substance abuse treatment and prevention activities and shall report activities taken in support of these goals and objectives in its application.

(5) The State shall submit a detailed description on the extent to which the availability of prevention and treatment activities is insufficient to meet the need for the activities; the interim services to be made available under sections 96 126 and 96 131 and the manner in which such services are to be so available. Special attention should be provided to the following groups:

- (i) Pregnant addicts
- (ii) Women who are addicted and who have dependent children
- (iii) Injecting drug addicts and
- (iv) Substance abusers infected with HIV or who have tuberculosis

(6) Documentation describing the results of the State's management information system pertaining to capacity and waiting lists shall also be submitted as well as a summary of such information for admissions and, when available, discharges. As to prevention activities, the report shall include a description of the populations at risk of becoming substance abusers.

§ 96 134 Maintenance of effort regarding State expenditures.

(a) With respect to the principal agency of a State for carrying out authorized activities the agency shall for each fiscal year maintain aggregate State expenditures by the principal agency for authorized activities at a level that is not less than the average level of such expenditures maintained by the State for the two year period preceding the fiscal year for which the State is applying for the grant. The Block Grant shall not be used to supplant State funding of alcohol and other drug prevention and treatment programs.

(b) Upon the request of a State the Secretary may waive all or part of the requirement established in paragraph (a) of this section if the Secretary determines that extraordinary economic conditions in the State justify the waiver. The State involved must submit information sufficient for the Secretary to make the determination including the nature of the extraordinary economic circumstances, documented evidence and appropriate data to support the claim and documentation on the year for which the State seeks the waiver. The Secretary will approve or deny a request for a waiver not later than 120 days after the date on which the request is made. Any waiver provided by the Secretary shall be applicable only to the fiscal year involved. Extraordinary economic conditions mean a financial crisis in which the total tax revenue declines at least one and one-half percent, and either unemployment increases by at least one percentage point, or employment declines by at least one and one-half percent.

(c) In making a Block Grant to a State for a fiscal year the Secretary shall make a determination of whether for the previous fiscal year or years the State maintained material compliance with any agreement made under paragraph (a) of this section. If the Secretary determines that a State has failed to maintain such compliance the Secretary shall reduce the amount of the allotment for the State for the fiscal year for which the grant is being made by an amount equal to the amount

constituting such failure for the previous fiscal year.

(d) The Secretary may make a Block Grant for a fiscal year only if the State involved submits to the Secretary information sufficient for the Secretary to make the determination required in paragraph (a) of this section, which includes the dollar amount reflecting the aggregate State expenditures by the principal agency for authorized activities for the two State fiscal years preceding the fiscal year for which the State is applying for the grant. The base shall be calculated using Generally Accepted Accounting Principles and the composition of the base shall be applied consistently from year to year.

§ 96 135 Restrictions on expenditure of grant.

(a) The State shall not expend the Block Grant on the following activities:

- (1) To provide inpatient hospital services except as provided in paragraph (c) of this section.
- (2) To make cash payments to intended recipients of health services.
- (3) To purchase or improve land, purchase, construct or permanently improve (other than minor remodeling) any building or other facility, or purchase major medical equipment.
- (4) To satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds.
- (5) To provide financial assistance to any entity other than a public or nonprofit private entity.
- (6) To provide individuals with hypodermic needles or syringes so that such individuals may use illegal drugs unless the Surgeon General of the Public Health Service determines that a demonstration needle exchange program would be effective in reducing drug abuse and the risk that the public will become infected with the etiologic agent for AIDS.

(b) The State shall limit expenditures on the following:

- (1) The State involved will not expend more than 5 percent of the grant to pay the costs of administering the grant and
- (2) The State will not, in expending the grant for the purpose of providing treatment services in penal or correctional institutions of the State, expend more than an amount prescribed by section 1931(a)(3) of the PHS Act.

(c) Exception regarding inpatient hospital services.

- (1) With respect to compliance with the agreement made under paragraph (a) of this section a State (acting through the Director of the principal agency) may expend a grant for inpatient

hospital based substance abuse programs subject to the limitations of paragraph (c)(2) of this section only when it has been determined by a physician that

(i) The primary diagnosis of the individual is substance abuse and the physician certifies this fact

(ii) The individual cannot be safely treated in a community based nonhospital, residential treatment program

(iii) The Service can reasonably be expected to improve an individual's condition or level of functioning

(iv) The hospital-based substance abuse program follows national standards of substance abuse professional practice and

(2) In the case of an individual for whom a grant is expended to provide inpatient hospital services described above the allowable expenditure shall conform to the following

(i) The daily rate of payment provided to the hospital for providing the services to the individual will not exceed the comparable daily rate provided for community based nonhospital residential programs of treatment for substance abuse and

(ii) The grant may be expended for such services only to the extent that it is medically necessary i.e. only for those days that the patient cannot be safely treated in a residential community based program

(d) The Secretary may approve a waiver for construction under paragraph (a)(3) of this section within 120 days after the date of a request only if

(1) The State demonstrates to the Secretary that adequate treatment cannot be provided through the use of existing facilities and that alternative facilities in existing suitable buildings are not available

(2) The State has carefully designed a plan that minimizes the costs of renovation or construction

(3) The State agrees with respect to the costs to be incurred by the State in carrying out the purpose of the waiver to make available non Federal contributions in cash toward such costs in an amount equal to not less than \$1 for each \$1 of Federal funds provided under the Block Grant and

(4) The State submits the following to support paragraphs (b)(1) (2) and (3) of this section

(i) Documentation to support paragraph (d)(1) of this section such as local needs assessments waiting lists survey data and other related information

(ii) A brief description of the project to be funded including the type(s) of services to be provided and the

projected number of residential and/or outpatient clients to be served

(iii) The specific amount of Block Grant funds to be used for this project

(iv) The number of outpatient treatment slots planned or the number of residential beds planned if applicable

(v) The estimate of the total cost of the construction or rehabilitation (and a description of how these estimates were determined) based on an independent estimate of said cost, using standardized measures as determined by an appropriate State construction certifying authority

(vi) An assurance by the State that all applicable National (e.g. National Fire Protection Association Building Officials and Codes Administrators International) Federal (National Environmental Policy Act) State and local standards for construction or rehabilitation of health care facilities will be complied with

(vii) Documentation of the State's commitment to obligate these funds by the end of the first year in which the funds are available and that such funds must be expended by the end of the second year (section 1914(a)(2) of the PHS Act)

(viii) A certification that there is public support for a waiver as well as a description of the procedure used (and the results therein) to ensure adequate comment from the general public and the appropriate State and local health planning organizations local governmental entities and public and private sector service providers that may be impacted by the waiver request

(ix) Evidence that a State is committed to using the proposed new or rehabilitated substance abuse facility for the purposes stated in the request for at least 20 years for new construction and at least 10 years for rehabilitated facilities

(x) An assurance that if the facility ceases to be used for such services or if the facility is sold or transferred for a purpose inconsistent with the State's waiver request monies will be returned to the Federal Government in an amount proportionate to the Federal assistance provided as it relates to the value of the facility at the time services cease or the facility sold or transferred

(xi) A description of the methods used to minimize the costs of the construction or rehabilitation including documentation of the costs of the residential facilities in the local area or other appropriate equivalent sites in the State

(xii) An assurance that the State shall comply with the matching requirements of paragraph (d)(3) of this section and

(xiii) Any other information the Secretary may determine to be appropriate

§ 96.136 Independent peer review

(a) The State shall for the fiscal year for which the grant is provided provide for independent peer review to assess the quality appropriateness and efficacy of treatment services provided in the State to individuals under the program involved and ensure that at least 5 percent of the entities providing services in the State under such program are reviewed. The programs reviewed shall be representative of the total population of such entities

(b) The purpose of independent peer review is to review the quality and appropriateness of treatment services. The review will focus on treatment programs and the substance abuse service system rather than on the individual practitioners. The intent of the independent peer review process is to continuously improve the treatment services to alcohol and drug abusers within the State system. Quality for purposes of this section is the provision of treatment services which within the constraints of technology resources and patient/client circumstances will meet accepted standards and practices which will improve patient/client health and safety status in the context of recovery. Appropriateness for purposes of this section means the provision of treatment services consistent with the individual's identified clinical needs and level of functioning

(c) The independent peer reviewers shall be individuals with expertise in the field of alcohol and drug abuse treatment. Because treatment services may be provided by multiple disciplines States will make every effort to ensure that individual peer reviewers are representative of the various disciplines utilized by the program under review. Individual peer reviewers must also be knowledgeable about the modality being reviewed and its underlying theoretical approach to addiction treatment and must be sensitive to the cultural and environmental issues that may influence the quality of the services provided

(d) As part of the independent peer review the reviewers shall review a representative sample of patient/client records to determine quality and appropriateness of treatment services while adhering to all Federal and State confidentiality requirements including 42 CFR Part 2. The reviewers shall examine the following

- (1) Admission criteria/intake process
- (2) Assessments

(3) Treatment planning including appropriate referral e.g. prenatal care and tuberculosis and HIV services

(4) Documentation of implementation of treatment services

(5) Discharge and continuing care planning and

(6) Indications of treatment outcomes

(e) The State shall ensure that the independent peer review will not involve practitioners/providers reviewing their own programs or programs in which they have administrative oversight, and that there be a separation of peer review personnel from funding decisionmakers. In addition, the State shall ensure that independent peer review is not

conducted as part of the licensing/certification process

(f) The States shall develop procedures for the implementation of this section and such procedures shall be developed in consultation with the State Medical Director for Substance Abuse Services

§ 96.137 Payment schedule

(a) The Block Grant money that may be spent for §§ 96.124(c) and (e), 96.127 and 96.128 is governed by this section which ensures that the grant will be the payment of last resort. The entities that receive funding under the Block Grant and provides services required by the above referenced sections shall make every reasonable effort including

the establishment of systems for eligibility determination, billing and collection to

(1) Collect reimbursement for the costs of providing such services to persons who are entitled to insurance benefits under the Social Security Act, including programs under title XVIII and title XIX, any State compensation program, any other public assistance program for medical expenses, any grant program, any private health insurance or any other benefit program, and

(2) Secure from patients or clients payments for services in accordance with their ability to pay

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