

Dept. of Health and Human Services

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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 retain 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.

§ 96.130 State law regarding sale of tobacco products to individuals under age of 18.

(a) For purposes of this section, the term "first applicable fiscal year" means fiscal year 1994, except in the case of any State described in section 1926(a)(2) of the PHS Act, in which case "first applicable fiscal year" means fiscal year 1995. The term "outlet" is any location which sells at retail or otherwise distributes tobacco products to

consumers including (but not limited to) locations that sell such products over-the-counter or through vending machines.

(b) The Secretary may make a grant to a State only if the State, for the first applicable fiscal year and subsequent fiscal years, has in effect a law providing that it is unlawful for any manufacturer, retailer, or distributor of tobacco products to sell or distribute any such product to any individual under age 18 through any sales or distribution outlet, including over-the-counter and vending machine sales.

(c) For the first and second applicable fiscal years, the State shall, at a minimum, conduct annually a reasonable number of random, unannounced inspections of outlets to ensure compliance with the law and plan and begin to implement any other actions which the State believes are necessary to enforce the law.

(d) For the third and subsequent fiscal years, the States shall do the following:

(1) The State shall conduct annual, random, unannounced inspections of both over-the-counter and vending machine outlets. The random inspections shall cover a range of outlets (not preselected on the basis of prior violations) to measure overall levels of compliance as well as to identify violations.

(2) Random, unannounced inspections shall be conducted annually to ensure compliance with the law and shall be conducted in such a way as to provide a probability sample of outlets. The sample must reflect the distribution of the population under age 18 throughout the State and the distribution of the outlets throughout the State accessible to youth.

(e) As provided by § 96.122(d), the State shall annually submit to the Secretary a report which shall include the following:

(1) a detailed description of the State's activities to enforce the law required in paragraph (b) of this section during the fiscal year preceding the fiscal year for which that State is seeking the grant;

(2) a detailed description regarding the overall success the State has achieved during the previous fiscal

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year in reducing the availability of tobacco products to individuals under the age of 18, including the results of the unannounced inspections as provided by paragraph (d) of this section for which the results of over-the-counter and vending machine outlet inspections shall be reported separately;

(3) a detailed description of how the unannounced inspections were conducted and the methods used to identify outlets;

(4) the strategies to be utilized by the State for enforcing such law during the fiscal year for which the grant is sought; and

(5) the identity of the agency or agencies designated by the Governor to be responsible for the implementation of the requirements of section 1926 of the PHS Act.

(f) Beginning in the second applicable fiscal year, the annual report required under paragraph (e) of this section shall be made public within the State, along with the State plan as provided in section 1941 of the PHS Act.

(g) Beginning with applications for the fourth applicable fiscal year and all subsequent fiscal years, the Secretary will negotiate with the State, as part of the State's plan, the interim performance target the State will meet for that fiscal year and in subsequent years will seek evidence of progress toward achieving or surpassing a performance objective in which the inspection failure rate would be no more than 20% within several years.

(h) Beginning with the second applicable fiscal year and all subsequent fiscal years, the Secretary shall make a determination, before making a Block Grant to a State for that fiscal year, whether the State reasonably enforced its law in the previous fiscal year pursuant to this section. In making this determination, the Secretary will consider the following factors:

(1) During the first and second applicable fiscal years, the State must conduct the activities prescribed in paragraph (c) of this section.

(2) During the third applicable fiscal year, the State must conduct random, unannounced inspections in accordance with paragraph (d) of this section.

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(3) During the fourth and all subsequent applicable fiscal years, the State must do the following:

(i) conduct random, unannounced inspections in accordance with paragraph (d); and

(ii) except as provided by paragraph (h)(4) of this section, the State must be in substantial compliance with the target negotiated with the Secretary under paragraph (g) of this section for that fiscal year.

(4) If a State has not substantially complied with the target as prescribed under paragraph (h)(3)(ii) of this section for any fiscal year, the Secretary, in extraordinary circumstances, may consider a number of factors, including survey data showing that the State is making significant progress toward reducing use of tobacco products by children and youth, data showing that the State has progressively decreased the availability of tobacco products to minors, the composition of the outlets inspected as to whether they were over-the-counter or vending machine outlets, and the State's plan for improving the enforcement of the law in the next fiscal year.

(i) If, after notice to the State and an opportunity for a hearing, the Secretary determines under paragraph (h) of this section that the State has not maintained compliance, the Secretary will reduce the amount of the allotment in such amounts as is required by section 1926(c) of the PHS Act.

(j) States may not use the Block Grant to fund the enforcement of their statute, except that they may expend funds from the primary prevention set-aside of their Block Grant allotment under 45 CFR 96.124(b)(1) for carrying out the administrative aspects of the requirements such as the development of the sample design and the conducting of the inspections.

[61 FR 1508, Jan. 19, 1996, as amended at 66 FR 46227, Sept. 4, 2001]

§ 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