DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 96

RIN 0930–AA01

Tobacco Regulation for Substance Abuse Prevention and Treatment Block Grants

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Final rule.

SUMMARY: On August 26, 1993, the Department of Health and Human Services (HHS) published a Notice of Proposed Rulemaking (NPRM) to implement section 1926 of the Public Health Service (PHS) Act regarding the sale and distribution of tobacco products to individuals under the age of 18. The Secretary requested comments on the NPRM and gave 60 days for individuals to submit their written comments to the Department. The Secretary has considered the comments received during the open comment period and is issuing the final regulation in light of those comments.

EFFECTIVE DATE: February 20, 1996.

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SUPPLEMENTARY INFORMATION: The Department is finalizing the rule entitled ''Substance Abuse Prevention and Treatment Block Grants: Sale or Distribution of Tobacco Products to Individuals Under 18 Years of Age,'' which was published as a NPRM in the Federal Register on August 26, 1993 (58 FR 55156). The final rule is developed in accordance with section 1926 of the PHS Act, 42 U.S.C. 300x–26, as amended.

Relationship to proposed Food and Drug Regulations Restricting the Sale and Distribution of Tobacco Products

On August 10, 1995, President Clinton announced the issuance of proposed ''Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents'' by the Food and Drug Administration (FDA) (60 FR 41314, Aug. 11, 1995). If promulgated, these regulations would restrict minors' access to nicotine-containing tobacco products and would reduce the amount of positive imagery that makes these products attractive to young people. The basis for FDA's tentative conclusion establishing its jurisdiction over these tobacco products is set forth in the FDA NPRM's accompanying proposed jurisdictional analysis. (Federal Register, Volume 60, No. 155, page 41453, August 11, 1995).

The final rule being issued today will complement and be consistent with any rule that FDA promulgates, when and if FDA does so. While this final rule is directed to the States and the FDA proposal focuses on the tobacco industry and retailers, they are both designed to help address the serious public health problem caused by young people's use of and addiction to nicotine-containing tobacco products. By approaching this public health problem from different perspectives, these actions together would help achieve the President's goal of reducing the number of young people who use tobacco products.

The regulatory approaches reflect major differences in the statutory authorities of the respective agencies. In addition to requiring States to have in effect laws which prohibit the sale of tobacco products to minors as a condition of receipt of a grant, this rule requires that States enforce such laws, and meet certain negotiated rates of compliance so as not to suffer a reduction in block grant allotments as prescribed by law. On the other hand, the FDA proposal addresses the conduct of tobacco manufacturers, distributors, and retailers. The FDA proposal seeks to reduce young people's use of tobacco by placing certain restrictions on the sale, distribution, advertising, and promotion of tobacco products to minors. Thus, these two regulatory actions both address the need to reduce minors' access to tobacco products, and the FDA proposal further attempts, through its advertising provisions, to reduce the powerful appeal of tobacco products to children and adolescents.

Background on the Notice of Proposed Rulemaking and Summary of Responses to Public Comment

A. Notice of Proposed Rulemaking

The NPRM proposed regulations to implement section 1926 of the PHS Act. Section 1926 provides that ''the Secretary may not make a [Substance Abuse Prevention and Treatment block] grant to a State for the first applicable fiscal year and all subsequent fiscal years unless the State has in effect a law prohibiting any manufacturer, retailer or distributor of tobacco products from selling or distributing such products to any individual under the age of 18.'' According to section 1926(a)(2), States are to have such laws in place for receipt of FY 1994 Substance Abuse Prevention and Treatment (SAPT) Block Grant funds unless a State's legislature does not convene a regular session in FY 1993 or 1994, in which case a State must have such a law in place for receipt of FY 1995 funds. The Secretary proposed to implement this statutory provision by requiring States to have in place a law that prohibits the sale or distribution of any tobacco product to individuals under the age of 18 (minors) through any sales or distribution outlet. This would include sales or distribution from any location which sells at retail or otherwise distributes tobacco products to consumers, including locations that sell such products over-the-counter or through vending machines. Beyond this, the Secretary did not propose specifying the provisions of the States' laws.

Section 1926(b) of the PHS Act requires States, as a condition of receipt of a grant, to enforce such laws ''in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to individuals under the age of 18.'' In enforcing such laws, section 1926(b)(2)(A) requires the States to conduct random, unannounced inspections. The NPRM proposed a regulation to require States to have ''well-designed procedures'' in place for reducing the likelihood or prevalence of violations. Examples of such procedures were provided in the regulation. The Secretary also proposed that the State, at a minimum, enforce the law using both random and targeted unannounced inspections of both over-the-counter and vending machine outlets. It was proposed that the random, unannounced inspections be conducted annually and be conducted in such a way as to ensure a scientifically sound estimate of the success of enforcement actions being taken throughout the State.

Section 1926(b)(2)(B) of the PHS Act requires the States to annually submit to the Secretary a report describing the strategies and activities carried out by the State to enforce such law during the fiscal year for which the State is seeking the grant, and the extent of success the State has achieved in reducing the availability of tobacco products to minors. The NPRM essentially requested this information. As part of such information, the NPRM proposed, among other things, to require States to report on the results of the unannounced inspections and to provide a detailed description of how the unannounced inspections were conducted and the methods used to identify outlets to be inspected.

Section 1926(c) of the PHS Act requires the Secretary to determine whether the State has maintained compliance with the enforcement requirements of the statute. If the Secretary determines that a State has not maintained such compliance, the Secretary is required to decrease the Block Grant from 10 to 40 percent depending on the fiscal year involved. In determining enforcement compliance, the Secretary proposed the following: the State must demonstrate that its random, unannounced inspections were conducted in a scientifically sound manner and the data submitted by the State in the annual report must show that the percentage of the retailers or distributors involved in the random, unannounced inspections making illegal sales does not exceed 50 percent during the first applicable fiscal year, 40 percent in the second applicable fiscal year, 30 percent in the third applicable fiscal year and 20 percent in the fourth applicable fiscal year and subsequent fiscal years. If a State does not maintain material compliance with the above-mentioned criteria, the Secretary, in extraordinary circumstances, may consider a number of other factors such as a scientifically sound survey indicating that the State is making significant progress toward reducing use of tobacco products by minors.

B. Public Comment and Department's Response

During the 60-day comment period that ended on October 26, 1993, the Department received 354 letters providing comments on the NPRM. These comments spanned a wide range of concerns and issues. They presented a complex mix of support for and opposition to the Department's proposal. The preamble sections below summarize these views and provide the Department's responses to them.

General Comments

Numerous commenters, including State agencies, State legislators and Governors, claimed the NPRM was redundant and unnecessary. They argued that States currently have laws in place that prohibit the sale of tobacco to minors, and they felt the Department was forcing the States to create redundant laws.

This regulation does not require redundant or duplicate laws at the State level; rather it requires that States have in effect a law providing that it is unlawful for any manufacturer, retailer or distributor to sell or distribute tobacco products to individuals under the age of 18. In the event that a State does not have such a law in place, one is required if the State wishes to receive an SAPT Block Grant. At the time of passage of section 1926 of the PHS Act, the majority of States had laws in place that complied with the requirement of section 1926(a).

Many commenters raised concerns about the short timeframe within which the regulation was to be implemented. These concerns primarily centered on the time it would take to develop an inspection sampling frame and to design and conduct inspections. The Department recognizes the difficulties States may face in complying with these requirements and enforcing their laws sufficiently to reduce the extent to which tobacco products are available to individuals under the age of 18, as required by section 1926. As discussed later in this preamble, States will be provided time to develop an effective inspection system.

Some commenters argued that the Department was not allowing retailers and States time to demonstrate the success of industry or other State programs designed to restrict youth access. The Department notes that the statute specifically requires that, for most States, enforcement of their laws must occur in FY 1994 and that States must enforce their laws in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to minors. Section 1926 also requires States to conduct random, unannounced inspections. The Department cannot, therefore, delay the implementation of these statutory provisions.

Several commenters argued that the Department should place responsibility on minors for complying with this law rather than targeting retailers with such responsibility. Other commenters took the opposing view and cautioned against requiring penalties against minors for purchasing tobacco products.

The statute does not give the authority to the Department to require laws prohibiting the purchase of tobacco products by minors nor to regulate the conduct of retailers. However, States are required under section 1922 of the PHS Act to develop primary prevention activities to reduce tobacco use by minors in keeping with 45 CFR 96.125. The Preventive Health and Health Services Block Grant, sections 1901, *et seq.*, of the PHS Act, administered by the Centers for Disease Control and Prevention (CDC) also provides assistance to States to implement strategies to prevent tobacco use among all populations, including minors. These prevention strategies targeted to minors will serve to reinforce the enforcement strategies required by section 1926.

Definitions

A number of commenters believed that, by specifically including vending machines in the definition of a retail outlet and by requiring a separate reporting requirement, the Department was proposing more stringent enforcement requirements on outlets than are required by the law. In addition, many commenters from State agencies argued that most States do not have legislation in place with regard to controls on vending machines and, therefore, that they would have difficulty complying with the regulation if it included vending machines as a type of outlet.

The Department defines ''outlet'' as ''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.'' The Department is requiring States to have laws in place during the first applicable fiscal year which make it illegal for a manufacturer, retailer, or distributor of tobacco products to sell or distribute any such products to an individual under the age of 18 through any sales or distribution outlet, including over-the-counter and vending machine sales. The Department believes that this construction of section 1926 of the PHS Act, i.e., covering vending machines, reasonably carries out the intent of Congress, and the Department believes that, if only over-the-counter sales were prohibited, minors would purchase tobacco products from vending machines as access to over-the-counter tobacco products becomes more difficult.

With respect to timing, we point out that States have now had several years since enactment of section 1926 and publication of our proposed rule, to pass necessary legislation and to take other steps to begin effective enforcement of their laws against sale and distribution to minors.

Random Unannounced Inspections

Many commenters suggested that the Department require States to use ''sting'' operations, in which minors would attempt to purchase tobacco products, either over-the-counter or from a vending machine, as the most efficient and effective method of carrying out such inspections. The NPRM gave the States flexibility in implementing the requirement for random, unannounced inspections, and it did not require ''stings.'' The Department sees no reason at this time to change that policy. While

there is considerable literature supporting the use of ''stings'' as an efficient and effective method of carrying out such inspections, there is no conclusive research to suggest that it is the only viable method that could be developed. Furthermore, the Department strongly supports giving States flexibility in devising methods to use in enforcing their laws.

However, the Department wants States to know that it does not know of any other valid alternative methods. Despite the NPRM's request for suggestions for alternative methods, and the many comments received opposing the use of ''stings,'' the Department has not identified evidence of any other workable or valid method of random, unannounced inspections for determining illegal sales. Moreover, the regulation's compliance level is based on the ''sting'' methodology, and the Department would need an empirical basis for converting results from one enforcement method to another to assess compliance.

In the light of these issues, the Department considered a range of options to protect both the States and the integrity of the program, including modifying the regulation to provide for formal approval by HHS of any alternative method. Another option would have been to specify in some detail either the methodology the Department would find acceptable or to define such terms as ''unannounced.'' Ultimately, the Department decided to leave the matter open and flexible, relying on the good judgment of State officials. The Department does, however, strongly urge any State that contemplates using an alternative method to work with the Department in advance of implementation to show that the method validly measures compliance through random, unannounced inspections, and to ensure that the inspection approach will produce the data necessary to determine that the State meets the compliance target.

Another large group of commenters opposed the use of minors in conducting compliance inspections because they feared that inspectors would attempt to entrap retailers by inspecting at busy times during the day, by attempting to purchase when the seller is distracted, by pressuring the seller, or by using individuals as decoys who do not look like minors. A number of commenters expressed concern that a child may not be sufficiently mature to understand undercover procedures and inadvertently entrap a retailer.

The Department is aware that entrapment may be a potential problem for retailers. Since the implementation of random, unannounced inspections is a State responsibility that is required by statute for receipt of an SAPT Block Grant, the Department expects States, if they choose to have minors participate in inspections, to develop procedures to address (and thereby avoid) these concerns and to educate officials regarding permissible and impermissible activities.

Many commenters argued that using minors in inspections could have a detrimental impact on minors participating in such operations (e.g., danger, exploitation). Among the fears expressed was the possibility of repercussions, in the event that the minor is discovered in his/her undercover role. Additionally, these commenters believed that undercover work is inherently dangerous and only to be undertaken by trained law enforcement officers. It was also feared that a child would be asked to take the witness stand and have to undergo cross examination.

The Department believes that the use of minors in inspections is very effective in gathering data and believes these inspections will show that proper training and adult supervision can reduce any potential risk of negative consequences toward youth. The Department does, however, expect States to provide all of the necessary precautions to safeguard the youth participants.

Commenters who favored requiring inspections involving the use of minors suggested the following guidelines: (a) minors should be supervised by adults, (b) minors should not be used in outlets they frequent or in their neighborhood so they may not be confronted later, (c) minors should not be involved in any confrontation with the retailer and, therefore, such confrontation should be made after the youth has left the store, and (d) minors should be 2–3 years younger in age and appearance than the legal age for purchase of tobacco products. Many commenters also suggested that minors be supervised by the State or an organization under contract to the State and that they be granted immunity from any State prohibition on the purchase of tobacco by minors.

Following publication of this rule, the Center for Substance Abuse Prevention (CSAP) will provide to States technical assistance and further guidance on state-of-the-art inspection processes, including guidelines, training and technical assistance, on which CSAP and CDC are collaborating. Comments on the NPRM are being considered in the development of these guidelines, training and technical assistance.

Several commenters urged the Department to make the inspection requirements more stringent. The Department believes that the inspection requirement as stated is sufficiently stringent to achieve the goals of section 1926 without imposing an undue burden on the States. Variations among States dictate the need for some flexibility in the design and conduct of the random, unannounced inspections.

A few of the Single State Agencies for alcohol and other drug (AOD) abuse prevention and treatment (SSAs) and some alcohol and other drug abuse providers that commented on the NPRM believed their involvement with the tobacco enforcement tasks of the law would hurt their position with the very citizens they aim to serve. They believed that clients would fear or avoid accessing services, because the providers would also be enforcing the laws.

First, it should be noted that section 1926 does not require that the inspections be performed by the SSAs or by the providers they contract with to provide AOD services. The required inspections may well be carried out by, or under the direction of, other agencies of State government. Moreover, even if SSAs do enforce the provision, the Department does not believe that they will drive away their target population or client base by implementing random, unannounced inspections. These inspections are not directed at individuals who purchase the tobacco products, rather at those who sell or distribute the products to youth. Neither the required law nor this regulation requires penalties against an individual for violating tobacco access laws. The Department feels that a client's perception of risk or fear of reprisal will be negligible and that AOD prevention and treatment providers will not be negatively impacted.

Comments were also received regarding the use of private entities performing inspections. The issue of State responsibility and accountability was raised regarding inspections conducted by private entities. Opponents raised concerns about ''vigilantism,'' since they believed that such inspections would be motivated by an anti-tobacco agenda and would be subjected to no formal accountability requirements. Supporters of the use of private entities to inspect outlets viewed such inspections as an assurance that individual citizens have the right to independently evaluate the State's progress. They argued that the public has the right to be involved in

inspections and feared any limitation on that right.

The Department does not require or prohibit the use of independent contractors or other type of organization to perform inspections of outlets for the State. It is the States' responsibility to demonstrate to the Department that random, unannounced inspections have been conducted in a fair, consistent, unbiased, planned manner that will provide useful data on the sale or distribution of tobacco products to minors.

Commenters offered numerous recommendations on alternate strategies for inspecting outlets. One commenter suggested using ''random inspections'' for scientific measures, ''routine inspections'' for compliance checks, and ''targeted inspections'' for enforcement of previous violators. Other recommendations included routine, pre-announced inspections and the inspection of outlet-sponsored ''give-a-way'' programs, as already specified by the NPRM.

While the Department believes that these suggested strategies are helpful, in the interest of providing States with appropriate flexibility, the Department will not prescribe how random, unannounced inspections are to be performed. Such approaches have been noted and may be included in further guidelines and training provided by the Department to inform States on all the options available to them in effectively carrying out these requirements.

Commenters argued that the targeted inspections required in the proposed regulation imply States' knowledge of prior violations and that such information does not currently exist and cannot be tested for in the first year. Others argued that targeted inspections exceed the intent of the law. Still others argued that targeted inspections should be required.

The Department has reviewed the proposed requirement for inspections targeted at outlets with previous violations. The Department believes that each State should have the flexibility to enforce its laws in a manner that can reasonably be expected to reduce availability of tobacco products to minors in light of that State's own unique circumstances. Therefore, we are not requiring that States conduct targeted inspections. States are reminded, however, that targeted inspections are an appropriate method of controlling youth access to tobacco products and may be considered by the Secretary in making a determination when a State is not found to be in substantial compliance with the State's negotiated inspection failure rate, which is discussed in more detail below.

Other Well-Designed Procedures

Many commenters argued that the proposed requirement for ''other well-designed procedures'' was excessive. Many commenters perceived the NPRM's requirement for ''other, well-designed procedures'' as forcing States to enact additional laws as a condition of funding, and thus exceeding the scope of the statute, congressional intent and Departmental discretion under the statute. Commenters further stated that existing laws and procedures are sufficient and that this requirement would necessitate new legislation that would interfere or conflict with existing laws.

Commenters representing SSAs claimed they would not be able to initiate ''other well-designed procedures'' in time to adequately comply with the regulation, especially since State legislatures meet briefly, or not at all, this year. Examples of procedures considered problematic and time-consuming to implement include licensing, controls on vending machines, and excise taxes. They believed that each of these procedures is a highly charged political issue and not easily passed legislatively. Some States argued that, given their need to enact enforcement legislation and the strength of the tobacco industry's opposition to such initiatives, they would need to receive an extension from the Department for compliance.

Many other commenters requested that the final rule mandate specific procedures (suggested strategies and examples found in the Preamble and the Model Law that was appended to it) rather than allow the flexibility provided in the NPRM. They stressed the need for a more stringent approach to the requirement and recommended that a wide range of mandates be included in the regulation, such as:

1. A tobacco sales or distribution licensing system;
2. A graduated schedule of penalties for violations;
3. A ban on vending machines;
4. Elimination of all vending machines in locations where minors have access; and
5. An updated version of the Model Law.

The Department has been persuaded by public comment to allow the States flexibility to determine which strategies are most appropriate for meeting the compliance target and enforcement requirements of the law and the regulation. To require ''other well-designed procedures'' at this time could, we believe, create unnecessary legislative obstacles for States, making it more difficult , not less, to achieve the goal of reducing the use of tobacco by youth. It would be counterproductive to the goal of increasing State enforcement activities if the final regulation were to require States to take additional legislative action to strengthen State tobacco control laws. We continue to believe that the adoption of ''other well designed procedures'' would enhance the effectiveness of State programs to curtail youth access to tobacco. However, during the initial phase of implementing this statute, State enforcement efforts will be more effective if States can devote time to the development of effective enforcement mechanisms without the additional burden of seeking legislative changes in State law. Therefore, the Department has eliminated the requirement of ''other well-designed procedures'' from the final rule.

The Department notes that the FDA's proposed regulations include several of the ''other well-designed procedures'' suggested in the preamble of the NPRM for this rule as well as other restrictions suggested by commenters (e.g., the elimination of vending machine sales and the prohibition of the sale of single cigarettes). The FDA proposal would not be directed toward affecting State laws. Rather, FDA proposes to affect the conduct of manufactures, distributors and retailers of tobacco products, a potentially effective and important means of reducing the numbers of children and adolescents who use and become addicted to tobacco products.

States should also be aware that, as part of each SAPT application, they are required to report what they have done to enforce the law during the previous fiscal year and what they intend to do during the fiscal year for which they are applying for funds. As discussed later, the Secretary may, in extraordinary circumstances, consider a number of factors other than the results of the random, unannounced inspections in determining compliance. One factor to be considered is the extent of the activities the State is carrying out in enforcing the law. Certainly, the suggestions in the preamble for the NPRM and the recommendations offered by commenters on the NPRM are viable ways that the States can enforce the provision.

States are reminded, however, that the Governor must assure the Department that the State will enforce its statute in a manner that will reasonably reduce the availability of tobacco products to minors. If a State fails to meet the negotiated compliance target as outlined

in this regulation and discussed below, the Department may seek additional information from such State before the Department will award the State a Block Grant. This information must be sufficient to provide reasonable assurance to the Department that the State will enforce its law, consistent with section 1926 of the PHS Act and the regulations.

Many comments focused attention on specific procedures that a State might implement and which were perceived by many as required. First, numerous commenters opposed the use of a licensing system for retailers. Some commenters opposed the NPRM's example of State licensing fees as a method of paying for the enforcement of this regulation, arguing that fees will hurt profits and lead to a loss of jobs. Commenters feared the regulatory nature of a licensing system, as States would be able to threaten retailers with suspension or revocation of their licenses for illegal sales of tobacco products by their employees. The licensing power, it is argued, could also be used to prohibit sales clerks under the age of 18 from handling tobacco products. Commenters also feared that a licensing system would allow regulators to pursue a broad anti-tobacco agenda. Finally, commenters believed that retailers would not be able to design and implement programs to comply with State and Federal substance abuse laws. Thus, they argued, a new, complex licensing program is not needed in order to limit the sale of tobacco products to minors. In contrast, many other commenters supported a licensing mechanism for the sale of tobacco. Some recommended a system with a graduated schedule of penalties for illegal sales, culminating in the loss of license.

The proposed regulation and Model Law explained how a licensing system could be used to enforce the States' laws effectively, with licensure fees and civil penalties funding both the random, unannounced inspections and other administrative costs. The Department did not, however, require a licensing system in the NPRM, and is not requiring one in the final rule. The Department believes, however, that a licensing system offers States an efficient method of identifying the total population of outlets for inspections and enforcement and that licensure fees can be a source of funds to pay for enforcement activities.

A small number of commenters recommended that the Department require either the elimination of tobacco vending machines or the elimination of vending machines in areas to which minors have access. They opposed the use of locking devices on vending machines because they believed such devices are ineffective. Other commenters supported using locking devices.

Bans and restrictions on vending machines and locking devices are viable options for States to consider in reducing tobacco sales to minors, but again, under this regulation the Department intends to allow States flexibility in the strategies they use to enforce tobacco control laws.

Several commenters opposed the Department's suggestion that States publish the names of, and boycott, outlets that have sold tobacco to individuals under the age of 18. They believed this is outside of the Department's authority and that such a suggestion should be removed from the regulation. Commenters argued that boycotts do not take into account attempts made by individual retailers to comply with the law.

The regulation does not require that States publicize the names or boycott outlets violating the law. However, studies have shown that these approaches can be effective in reducing violations (e.g., Turrisi, R.; Jaccard, J.; ''Cognitive and Attitudinal Factors in the Analysis of Alternatives to Drunk Driving,'' *Journal of Studies on Alcohol* 53(5) p. 405–414, 1992) and, therefore, are options a State may want to consider.

A number of commenters requested the elimination of the ''Model Law'' from the NPRM, arguing that, since the NPRM is a Federal document that ties compliance to funding, examples and suggestions were viewed as legal demands. Topics in the Model Law that received considerable comment included registration/licensure fees, suspension and revocation of licenses, licensure of outlets under common ownership, and graduated penalties against violators of the law.

The Model Law is not a required element of the regulation. The Department published both the Model law and the Inspector General's report with the NPRM to provide the public with further information regarding its position on the issue of youth access to tobacco products and to foster discussion at the State level about various legislative strategies for ensuring the enforcement of tobacco access laws. These documents will not be published with this final rule but will continue to be made available.

Commenters gave considerable attention to the issue of restricting local jurisdictions from passing more stringent statutes. They recommended that the Department require States to permit local governments to enact and enforce, as strong or stronger, local tobacco control laws to supplement the State's enforcement activities. Some commenters on this issue requested that the Department recommend a decrease in funding to any State that limits the power of local governments, as the Federal requirements should be seen as a minimum standard for tobacco access and control.

Many States currently preempt localities in enforcing or implementing some forms of tobacco control activities. However, as noted in the NPRM, the Federal statute and regulation are minimum requirements to which the States are held. In no way should they be considered as limiting, or requiring States to limit, the powers of local governments to enact or enforce tobacco control laws. As shown in the DHHS Inspector General's report (''Youth Access to Tobacco,'' Office of the Inspector General, U.S. Department of Health and Human Services, OEI–01–92–00880, page 7, August 1992), the majority of minors laws and enforcement efforts regarding the sale of tobacco have taken place at the local level. The Department encourages States to allow localities the flexibility to enact stricter laws or to more rigorously enforce tobacco control laws. However, in the interest of allowing States flexibility in implementing the law, the Department will neither prohibit the States from preempting, nor require them to preempt, local initiatives on youth access to tobacco products.

Some commenters representing a variety of interest groups argued that State AOD agencies do not have the authority to enforce the law, nor should they be involved in the enforcement of this law. Commenters also argued that law enforcement agencies are stretched so thinly that they would not be able to provide the needed support. Effective enforcement would, they suggested, require the creation of a large, costly, ''bureaucratic,'' State-wide authority, which they believe is contradictory to the AOD agencies' mission.

The Department does not specify which agency within the State is to be responsible for implementing the law. Enforcement of the law may be done by enforcement agencies, SSAs, private entities, or a combination of these and other organizations. The Department expects the Governor of each State to designate the most appropriate agency to assume lead responsibility for implementing these requirements.

It is, however, appropriate for the SSA to work with other State agencies to ensure that tobacco access laws are

enforced at the State level, as well as to work closely with State legislators and law enforcement entities to ensure that youth access and enforcement laws are being met. Each State will have to consider the relative resources and capabilities of its various State entities and make a determination as to the most appropriate enforcement agency. So as to provide the Department with sufficient information on the strategies to implement the law, the Department in its final rule requires that each State report in future applications on the agency or agencies designated by the Governor to be responsible for implementing the requirements of Section 1926.

Annual Reporting

A few commenters recommended that the Department establish stronger inspection requirements (e.g., three levels of inspection, more clear requirements for performing inspections, fewer inspection violations before the Department reduces funding, and the creation of a system of penalties against outlets), and that the States be required in their application materials to describe these activities in detail.

The Department is confident that the inspection process as outlined in the final rule is sufficient for determining whether the States are complying with the regulation. States on their own may choose to implement more stringent inspections and if they do, States are to explain what they have done in their application. In carrying out more stringent inspections, however, States should make sure that they can provide the information the Secretary requires in this regulation in order to make a determination of compliance.

Many commenters recommended greater specificity in the reporting requirements being made by the Department. The Department does not agree. The Department is requiring the States to provide information sufficient to meet the requirements of the regulation and no more. To require that States submit additional information, even though that information is not necessary for determining the completeness of the application or compliance with the criteria established in this regulation, would put an undue burden on the States.

Several commenters disagreed with the requirement for separate reporting for over-the-counter and vending machine sales in the annual report. They argued that it is excessive and implies a separate compliance target for over-the-counter and vending machine sales.

The Department believes that the commenters misunderstood the reporting requirements at issue. It should be noted that the Department is basing compliance on the aggregate results of both over-the-counter and vending machine inspections. The separate reporting requirements permit a better analysis of the results, and they allow the Secretary, in extraordinary circumstances, to consider the make-up of the outlets inspected in determining compliance, if the State does not meet the performance target as negotiated with the State. Of course, if the proposed FDA regulations' prohibition of vending machine sales goes into effect, we will revise our reporting forms to reflect this change. In the event a State prohibits vending machine sales of tobacco, the State will not have to include nonexistent vending machines in its sample or enter any data for vending machines.

Public Comment

There were several comments on the requirement that public comment shall be obtained and considered by the State prior to its submission of a report to the Secretary; most such comments were in favor. Those that disagreed were concerned about the burden thus represented and the timelines for reporting.

Section 1941 of the PHS Act requires States to offer the public an opportunity for comment on the State SAPT plan. In addition to this requirement, the final rule requires each State to submit for public comment the elements of the SAPT Block Grant report that relate to implementing this regulation. The Department does not believe that this is an excessive burden on the States nor that it will create any unnecessary delay in the submission of applications, since the States can send this portion of the report out for public comment at the same time, and in the same way, as they send the plan.

Scientifically Sound Sampling Frame and Design

Many comments were received regarding the requirement for a scientifically sound estimate based on an adequate sample design of the inspection effort. The majority of the commenters disagreed with this requirement. Both those who agreed with the requirement and those who disagreed were concerned about the States' ability to carry out this requirement without greater specificity, time and funding. Many of the commenters believed for these reasons that the sampling requirement is not fair, is unrealistic or is confusing. Many of the commenters recommended that the States either be given more time to develop scientifically sound estimates of success, be given more flexibility, or that the requirement be eliminated.

A few commenters made specific suggestions as to how to improve the guidance on sample design, including mandating inspections that would assure adequate representation of the universe, and requiring that the sample represent the ethnicity, gender and age distributions of the community in which the purchases are made.

The Department believes that it is necessary for the States to conduct probability samples of outlets to be inspected so that the Department has a reliable measure of how the law is being enforced throughout the individual States. The Department does not believe the States should be permitted to focus their efforts on locations that are unlikely to have a substantial population of underage persons. A requirement to draw a probability sample also will ensure that the States select outlets accessible to youth. The Department is available to provide technical assistance, training and guidelines with regard to the development of the sample designs.

Some commenters believe that the requirement for a scientifically sound sampling frame and design implies State enactment of licensure laws to provide a sampling base, since the regulation does not provide a clear design for a scientifically sound sampling frame.

The Department believes there are a variety of methods whereby a State may develop a sound sampling design in the absence of a licensing or formal registration system. At the outset, it should be noted that, sample designs will vary by State. States with complete centralized license lists can use these lists in developing a sampling frame. Other States can utilize commercial business lists that can be purchased from a variety of sources. These lists may not be as complete as license lists (particularly for small businesses and street vendors), in reflecting the total universe of tobacco outlets in the State, and, therefore, States may have to supplement them. Other options, which are not as desirable and may have to be supplemented include area sampling, community sampling, or sampling from Bureau of Alcohol, Tobacco, and Firearms (BATF) tax rolls.

It should be noted that the Department views an outlet as any ''location'' which sells or distributes tobacco products. The Department will consider for sampling purposes multiple sales points within one location to be a single outlet. For example, a motel that

has a shop that sells tobacco products over the counter, and has several vending machines which also sell tobacco products, would be considered one location.

Oversampling

Some commenters were concerned about the requirement that the distribution of inspection sites reflect the distribution of minors in the States, and that inspections be conducted at times when, or locations where, minors are more likely to purchase, (e.g., near schools, in malls, movie theaters, etc.). This requirement is viewed as complicating the process of determining and collecting baseline and effectiveness data and increasing the overall costs of performing inspections. The Department does not wish to put unnecessary obstacles in the paths of states wishing to achieve the compliance goal of the regulation and reduce illegal tobacco sales to minors. The Department believes there are many ways States can ensure that the inspections are conducted in such a way as to ensure an appropriate probability sample of outlets which are accessible to youth and is revising the regulation to reflect this change.

Timeframe

Numerous commenters argued that the Department is not allowing States adequate time to comply with the law and the proposed regulation, specifically with required inspections, reporting, and implementation of ''other well-designed procedures.'' Although many commenters believed that compliance with the inspection percentage targets is attainable, many claimed the Department is not accounting for the lead time necessary for a State to make the required legislative changes and to establish inspection sampling designs and systems.

The Department agrees that additional time is needed by States to implement an inspection process and to make the legislative and procedural changes that may be necessary for effective enforcement of their youth access laws. The Department is, therefore, revising the regulation so that for the first and second applicable fiscal years, the State must, 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.

For the third applicable fiscal year and all subsequent fiscal years, the States are to conduct annual, random, unannounced inspections of both over-the-counter and vending machine outlets. These random, unannounced inspections are to 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. Random, unannounced inspections are to be conducted in such a way as to conform to commonly accepted statistical standards and confidence levels.

Implementation of the negotiated percentage targets will not begin until the fourth applicable fiscal year as discussed in the next section. The Department expects that while some States will quickly achieve the *Healthy People 2000* objective for retail enforcement, others will have greater success in reaching this goal if given additional time to design and initiate enforcement of their statutes.[1] Further, the Department believes that this compliance schedule accommodates the needs of States for a reasonable period of time to organize their enforcement activities.

Compliance

Some commenters believed that the Department had exceeded its authority in establishing performance criteria and suggested that the Department only require that States make a good faith effort to enforce the laws. Several other commenters suggested that the standards should be based on State-specific baselines, while several others suggested the standards should disallow State-specific measures and develop national standards. Several commenters believed that the States are being held accountable for a Federal approach, that the standards do not take into consideration the variance among States and do not recognize their differences.

The Department continues to believe that the national objective should be to substantially reduce illegal sales of tobacco products to minors, and we believe that all States can make significant progress in reducing illegal tobacco sales if reasonable actions are taken to enforce each State's statute. We recognize that enforcement of existing State statutes cannot, in isolation, achieve the President's goal for significantly reducing the initiation of tobacco use by children and adolescents. Meaningful enforcement of State laws does, however, constitute an important step in reducing the availability of tobacco to children and youth.

After considering the circumstances that now exist in the States, we believe that achieving a 20 percent failure rate in the random, unannounced inspections required by the statute is a reasonable objective towards which States should strive. State enforcement of access laws can significantly reduce tobacco use by children. We are, however, convinced that the best results that can be obtained under this regulation will be achieved by allowing States flexibility in designing enforcement strategies to reach the 20 percent goal for retail enforcement recommended in Healthy People 2000. Therefore, the Department is establishing a 20 percent failure rate as a performance objective that States should achieve within several years, subject to some variation in schedule. After carefully considering the public comment on this issue, the Department now believes that establishing a flexible schedule that is adapted to the needs of individual States for the uniform schedule proposed in the NPRM strengthens the regulation. Tailoring the timetable to the circumstances of the States enables the Secretary to establish quicker schedules for those States which have already made substantial progress in enforcing their statutes. Somewhat longer periods of time are more appropriate for the States that have further to go. Providing these States additional time in the initial phase of implementing their enforcement activities will increase the chance that they will succeed in achieving the goals rather than fail.

To ensure that States are working toward meeting and exceeding that objective, but allow some variation in time to achieve it, the Secretary will negotiate annually with each State an interim performance objective the State should meet each year. It is our expectation that all States will reach and surpass the performance objective of 20 percent within several years. The target level negotiated with each State should demonstrate each State's commitment to furthering the ultimate goal of reducing tobacco use by underage youth, reasonably reducing the availability of tobacco products to minors and showing immediate and sustained progress toward meeting the 20 percent performance objective.

[1] U.S. Department of Health and Human Services, Public Health Service, *Healthy People 2000: Midcourse Review and 1995 Revisions*, DHHS Publication No. 017–001–00526–6 (Washington, D.C.: U.S. Government Printing Office, 1995), p. 173. Services and Protection Objective 3.13 proposes to ''enact in 50 States and the District of Columbia laws prohibiting the sale and distribution of tobacco products to youth younger than age 18. Enforce these laws so that the buy rate in compliance checks conducted in all 50 States and the District of Columbia is no higher than 20 percent.''

The results of the random, unannounced inspections in the third applicable fiscal year (which are to be conducted in such a way as to provide a probability sample of outlets that youth are likely to frequent) will serve as the base line. State specific maximum failure rates will be negotiated for the first time for applications for the fourth applicable fiscal year which for most States is FY 1997. States are encouraged to complete their inspections for the third and all subsequent applicable fiscal years in time to permit negotiations for the next fiscal year's application.

Comments on the compliance standards (allowable rate of inspection violations) were mixed. A large number of commenters requested that the compliance standards be made more stringent. They provided several suggestions on how the standards could be strengthened, particularly in the fourth year and beyond (either five percent or ten percent failure rates).

Several commenters suggested that the Department eliminate the compliance standards, stating that they are too stringent, arbitrary or prescriptive. A few stated that the standards will serve as a disincentive to accurate enforcement and reporting. A few commented that the standards will be impossible to evaluate. Some expressed concern that this approach could result in enforcement by the Department rather than by the States.

Several commenters argued that the States are being held accountable for compliance standards founded on faulty premises established by precursor studies conducted at the local level, and that the resulting reduction in the failure rate of random, unannounced inspections cannot be applied to the State level. Further, they argued that the reduction in the number of inspection failures resulted from public education and notification of inspection efforts.

The goal of the statute is to reduce the extent to which tobacco products are available to minors, which is critical to reducing tobacco use among minors. The Department believes to achieve a meaningful reduction in illegal tobacco sales to minors there must be a measurable performance objective. As discussed below, the Department has selected 20 percent as the appropriate objective.

The Department has decided, however, based on the comments received that a more effective and efficient program will result from eliminating the one-size-fits-all standards proposed in the NPRM that would establish a uniform schedule of annual failure rate reductions from 50 to 40 to 30 to 20 percent. In its place, the Secretary will negotiate a strategy with each State for achieving the performance objective over a period of several years. The Department believes this approach offers States the flexibility needed to achieve the objective. We would hope, of course, that when each state achieves the 20 percent performance objective, they would continue to seek even lower levels, eventually eliminating illegal sales to minors.

With regard to setting the performance objective at 20 percent, while there has been little experience with State level enforcement and, therefore, no studies to document appropriate expectations for State-wide inspections, the Department believes that the local studies do provide a reasonable starting point. Several studies in which unannounced inspections were used to measure access by minors to tobacco products show a significant reduction in the availability of such products when enforcement is strengthened. These studies reflect a sales rate of tobacco products to minors of 24 percent to 39 percent within one to two years of such enforcement efforts (see studies cited in NPRM, 58 FR 45157). Other studies have shown that moderate enforcement efforts such as officially sponsored ''stings'' and citations led to levels of illegal sales of close to zero percent (see discussion in economic analysis, below). These studies suggest that States using reasonable enforcement measures should be able to reduce illicit sales of tobacco products to minors to 20 percent or below over a relatively short period of time. Under the final rule, that time period will be negotiated with each State.

The Department will also work to assist States by supporting research and providing technical assistance helpful in determining the type of enforcement measures and control strategies that are most effective. This information will be helpful to States in improving their enforcement measures and further reducing their failure rates.

Many commenters expressed concern that all retailers were being held accountable for the mistakes of a few and that the sampling frame would only result in a suggested or ''estimated'' overall compliance level against which penalties would be determined. They were concerned about the use of a sample to ''estimate'' overall compliance.

It appears that these commenters misunderstood the Department's intent. The penalties prescribed by section 1926(c) of the PHS Act are applied to the State by means of a reduction in the amount of the SAPT Block Grant funds they receive. The penalties are not applied to retailers.

Secretary's Discretion

Several commenters expressed concern regarding the discretion given to the Secretary in determining compliance in extraordinary circumstances. They feared that such discretion will ultimately undermine the intent of the regulation. A number of commenters raised issues regarding cases in which a State does not meet the compliance criteria. A large number thought that the term ''substantial'' should be deleted because it undermined the Department's ability to carry out the penalties stipulated in the law. From the alternative perspective, a few commenters believed that the significant efforts, activities and progress of the States should be considered by the Secretary in making a compliance determination. A few thought a waiver should be given only after a public hearing. Lastly, there were a few commenters who suggested that the Department require enactment of one or more of the ''other procedures'' cited in the NPRM in the event that either a State is found out of compliance after the first year, or that waivers not be applied, in the event that the State failed to enact the recommended ''other well-designed procedures.'' The regulation permits the Secretary to, in extraordinary circumstances, consider other factors in determining compliance with the regulation, in the event that the State fails to adequately comply with the requirements. As indicated these will only be considered in extraordinary circumstances. In these instances, the Department will review a number of factors including appropriate survey data indicating that, in the previous year, significant progress has been made toward reducing the use of tobacco products by minors. It will be the responsibility of the State to explain the extraordinary circumstance and to provide the information for the Secretary to consider.

Moreover, the Department reminds the States that the Secretary, in extraordinary circumstances, may consider other well-designed procedures, in addition to the overall success a State achieves in reducing the availability of tobacco products to minors, in making a determination regarding a State which does not meet its negotiated goal. The Department recognizes that some States may implement other approaches, along with their inspection system, which may effectively reduce youth access and use

of tobacco products. The Secretary may also consider the State's efforts with respect to targeted inspections and enforcement measures toward those outlets known to be selling or distributing tobacco products to minors.

The Department notes that this discretion would be used in only extraordinary circumstances, and a State must clearly document the information that it wishes the Secretary to consider in determining whether to exercise that discretion. The Department believes that allowing the Secretary to take other factors into consideration, in extraordinary circumstances, will not undermine the intent of the law which is to reduce youth access to tobacco products.

Compliance Penalties

Several commenters expressed concern about the reduction in the Block Grant allotment for non-compliance. They considered the reduction to be punitive, unfair and too prescriptive. They further stated that the reduction would weaken or harm the alcohol and other drug abuse prevention and treatment systems. Lastly, they expressed concern that the State AOD agencies have no control over the situation since they are neither responsible for tobacco programs nor for law enforcement.

The Department appreciates the concerns expressed regarding the potential reduction in the Block Grant allotment and the negative impact of such a reduction on the alcohol and other drug abuse prevention and treatment systems. However, the Department also recognizes the importance of strong incentives for meeting the performance objective and notes that the reduction in allotment for non-compliance is legislated and not subject to change through the regulatory process.

Funding

Many commenters opposed this regulation with the argument that it imposes an unfunded mandate upon States from the Federal Government, in contradiction of the Administration's policies on unfunded mandates.

Commenters representing a wide variety of groups had serious concerns about how to fund the overall implementation of § 1926, especially the random, unannounced inspections. Many opposed the regulation, fearing they would be forced to pay for enforcement, such as merchants who believed that they would bear the cost of implementing and enforcing this regulation through licensing fees and penalties. State agencies believed they would be forced to shoulder the costs by diverting funds away from AOD prevention, treatment and other law enforcement activities. They claimed that alcohol and other drug abuse programs and violence programs would have to be cut, in order to pay for the enforcement of tobacco laws. Government representatives believed that taxes would have to be raised or licensure fees enacted to comply with the regulation. Several argued that Block Grant funds, or Federal funds from another source, should be used to pay for the cost of complying with this requirement.

Many commenters objected to the restriction on the use of the Block Grant program funds. Many commenters also argued that the five percent allotment for administrative expenses is already too small for current administrative costs of the Block Grant, without factoring in tobacco law enforcement. They feared that tobacco law enforcement would force AOD programs to be cut, and that some States would not be able to comply. Others argued that youth access should be considered a prevention activity and, therefore, the Block Grant program funds should be used to fund the enforcement.

Many expressed concern that the sampling frame requirement is costly, time-consuming, and labor-intensive. Commenters additionally argued that the cost involved for the enforcement of this law may result in a shift of resources out of needed, publicly accepted alcohol and other drug abuse prevention, treatment and enforcement activities into tobacco enforcement. They argued that social services and law enforcement are often housed in agencies other than those administering the SAPT Block Grant, giving them no inherent stake in complying with the regulation, especially since the cost for enforcement is expected to be high.

The Department recognizes the difficult funding decisions and the need to balance competing program priorities which States will face in order to implement this law. Inspections and enforcement are, however, requirements of the law, requirements that the Department cannot waive.

The Department wishes to explain the availability of Federal Block Grant funding for implementation of these statutory requirements. States may use funds from the Centers for Disease Control and Prevention's Preventive Health and Health Services Block Grant (42 U.S.C. 300w, *et seq.*), for sample design, inspection and other enforcement purposes, as funds from this block grant are available to assist States in conducting activities consistent with making progress toward achieving the objectives established by the Secretary for the health status of the Nation's population for the year 2000.[2]

States may also use funds from the primary prevention setaside of their SAPT Block Grant allotment, under 45 CFR 96.124(b)(1), to fund their sample design and inspection costs. States may not, however, use funds from the SAPT Block Grant to pay for other activities. To allow States to use SAPT Block Grant funds for such activities as court costs, for example, could significantly reduce the amount of funds available for substance abuse services.

Other Comments

The Department, in numerous instances in the NPRM, requested input and suggestions from commenters on feasible, objective, cost-effective approaches to enforcement of the law and compliance with the regulation. Commenters provided the Department with a large number of recommendations, in the following categories:

(1) Control of Tobacco Products

a. States should eliminate all forms of free distribution (samples, coupon redemption, etc.);

b. States should require all tobacco products to be kept behind the counter at outlets;

c. States should ban the sale of single cigarettes;

d. States should use locking devices on vending machines;

e. States should not use locking devices on vending machines; and

f. States should require that all tobacco products to be kept *locked* behind the counter.

(2) Educational Activities

a. States should provide public information and education campaigns on the prohibition of sales and distribution of tobacco; and

b. States should offer prevention and education activities.

(3) Procedural Activities

a. States should detail procedures for retailers to comply with the law (signs notifying public of law, request for ID, etc.);

[2] Section 1904(a)(1)(A) of the Public Health Service Act (42 U.S.C. 300w–3) authorizes the use of Preventive Health and Health Services Block Grant funds for "Activities consistent with making progress toward achieving the objectives established by the Secretary for the health status of the population of the United States for the year 2000. See also *Healthy People 2000: Midcourse Review and 1995 Revisions*, DHHS Publication No. (PHS), pp. 35–39.

b. Outlets should check the identification of all tobacco purchasers; and

c. Outlets should check State-issued identifications.

(4) Assessment/Survey Activities

a. States should base local assessments on the cost of sting operations;

b. States should base local assessments on passive observations of apparent age of purchasers; and

c. States should use self-report data from minors via survey questions about their success at purchasing tobacco products.

(5) Punitive Activities

a. States should allow for community action taken against violators;

b. States should increase fines for violations;

c. States should not punish minors for violating the law; and

d. States should punish minors for violating the law.

Although this regulation will not require that States implement such activities, States may wish to review this list of suggestions as possible activities or approaches to reduce the likelihood of violations of the law, as well as to reduce the use of tobacco products by children and youth.

Economic Impact

Executive Order 12866 requires the Department to analyze the costs and benefits of any regulation that is likely to have an economic impact of $100 million or more or meet other thresholds specified in the Order. In this assessment, the Department is to pay particular attention to the consistency of the regulatory action with the statutory mandate, and to avoiding interference with State, local, and tribal governments in the exercise of their governmental functions (§ 6(a) of the Order). In addition, as required by the Regulatory Flexibility Act, the Department prepares a Regulatory Flexibility Analysis for any regulation that is likely to have a ''significant'' economic impact on a ''substantial number'' of small entities, and analyze alternatives that may lessen impact on them. In the preamble to the proposed rule, the Department estimated compliance costs at about $50 million for States and up to $100 million for private business, and benefits at potentially billions of dollars a year. In the analysis that follows, the Department has summarized the original analysis, responded to comments on it, and incorporated additional information, including a discussion of the use of Block Grant funds to pay for the sample design and inspection requirements of this statute. Together with the remainder of the preamble, this assessment constitutes compliance with each of these legal requirements. This rule was reviewed by OMB pursuant to Executive Order 12866 as an economically significant regulatory action.

The FDA has independently estimated the effects of its proposal (drawing both on original analysis and substantial additional information), and the economic analysis and background information provided in its NPRM are presented in considerably greater depth than that presented here. The conclusions in both analyses are broadly consistent.

The Centers for Disease Control and Prevention (CDC) estimates that at present approximately 1 million underage youth and children become regular smokers each year. A major cause is ready, illegal access to tobacco products. Three-fourths or more of all outlets sell illegally to minors, due in part to insufficient enforcement efforts, which encourage a scoff-law attitude among merchants. A recent study (''Design of Inspection Surveys for Vendor Compliance with Restrictions on Tobacco Sales to Minors,'' April 1994, prepared by Rick L. Williams *et al.* of the Batelle Corporation) estimates that 73 per cent of all over-the-counter outlets and 96 per cent of all vending machine outlets sell tobacco products to minors.

The Department believes that aggressive and consistent enforcement efforts by States are likely to reduce substantially illegal tobacco sales. However, in the absence of tobacco control measures reducing availability and the allure of tobacco products to youth, State enforcement activities may not be fully effective. In addition, even the most successful enforcement activities may lead to partially offsetting tactics by youth, such as older youth legally buying cigarettes and reselling or giving them to younger youth. In such an event, the actual impact of more effective State enforcement may not achieve maximum progress in meeting the goal of reducing the use of tobacco products by youth and children. Furthermore, the volume of illegal sales is likely to vary depending on the number and location of stores which continue to sell illegally. If, for example, the proportion of outlets selling to minors were to be reduced by two-thirds, and there are three outlets located within a two block area, it is likely that youth would have access to tobacco at one of these three outlets. Although the effect on the number of outlets selling tobacco to youth may be substantial, the inconvenience to youth might be so small as to reduce illegal sales only slightly. Thus, the potential range of outcomes under serious enforcement may vary in the extent to which it affects the prevalence of youth smoking.

Estimates of annual spending on cigarettes by youth range from about $500 million to over $1.5 billion. (See consumption estimates by DiFranza, J and Tye, J, ''Who Profits from Tobacco Sales to Children?'' JAMA, 263:20 (1990): 2784–2787; and Cummings, K.M. et al., ''The Illegal Sale of Cigarettes to U.S. Minors: Estimates by State'' American Journal of Public Health 84:2 (1994): 300–302.) Whereas the original economic analysis used the higher estimate, this analysis relies on the lower figure presented in the more recent study. Thus, as little as a 20 percent total reduction in sales would have an economic effect of $100 million.

In light of the penalty provision contained in the statute, States will have a strong incentive to reduce the level of illegal sales. The outcome, however, will depend on the nature and extent of the enforcement actions taken by the States and, if the FDA proposed restrictions on access and appeal were made final, the synergistic effect such efforts would have when combined with such additional control measures, and with any supplemental tobacco control measures the States may adopt.

In addition to overall reductions in tobacco sales, enforcement of the law will affect the retail market. The money which would have been spent on tobacco products will be spent on other goods and services. An equivalent amount may be spent in the same stores which sell tobacco products. However, in some instances (e.g., sales from free-standing vending machines) it is not clear that alternative products will raise the same volume of revenue for a specific store. Therefore, the statute and the final rule may have a significant effect on some small businesses that currently sell tobacco products to minors.

In this analysis, the Department focuses mainly on cigarette sales, which account for the overwhelming majority of tobacco product sales to youth. Almost all of the analysis is, however, equally applicable to snuff and chewing tobacco.

Magnitude of Effects

For purposes of the analysis, the Department assumes that States will take significant actions to reduce the number of outlets selling tobacco products illegally, achieving a rate of

illegal sales below 20 percent within five years. Since about three-fourths of all retail stores and almost all vending machine outlets now sell to minors, a State could suffer a serious financial penalty if it failed to bring the great majority of these outlets into compliance within the specified periods. Based on limited data, the Department is aware that some localities have been highly successful in reducing failure rates to relatively low levels. For example, the Department is aware of one community—Woodbridge, Illinois—that used a variety of control methods to reach a failure rate of less than 5 percent. While State compliance results may not typically reflect the actual rate of sales to minors, cigarette use by youth decreased by half in this same community, despite the availability of outlets selling illegally in adjoining areas. In another community—Everett, Washington—a similar youth access effort had smaller effects on tobacco use. Unfortunately, there is no scientific basis on which to make a definitive statewide or national projection, absent a history of far stronger enforcement efforts by States and across a wider range of communities.

The Department expects that actual violation levels in most States, after successful implementation of State enforcement programs, will be driven lower than the percentage compliance targets to be negotiated for the short run. The Department does not know, however, what level of compliance the States will achieve on average, or precisely how that level will translate into reductions in youth smoking. It is probable, however, that the reduction in tobacco use by youth and children would be much less than the reduction in illegal sales measured by the State's failure rate. In the original economic analysis the Department suggested that a one-third to two-thirds reduction in smoking might be possible through improved enforcement. The Department now believes that a significantly lower estimate is more realistic given the uncertainties implicit in varying levels of State enforcement and the absence of meaningful controls on tobacco advertising and promotion.

The economic analysis in FDA's proposed regulations implicitly considered the impact of State programs in concluding that ''if aggressively implemented and supported by both industry and public sector entities, comprehensive programs designed to discourage youthful tobacco consumption could reasonably achieve the *Healthy People 2000* goal of halting the onset of smoking for at least half, or 500,000, of the 1,000,000 youngsters who presently start to smoke each year.'' [3] However, in the absence of adequate empirical data, FDA could not determine the independent contribution of each proposed restriction. Similarly, in view of the substantial uncertainty regarding future State enforcement efforts, the potential for offsetting industry promotional tactics, and the willingness of older youth to purchase tobacco products for younger youth, the Department is unable to make a precise quantitative estimate of the impact of this regulation on youth smoking rates. The Department expects, however, that any plausible estimate would exceed one-tenth, but fall short of one-third. Nevertheless, the analysis below demonstrates that even very modest declines in the rate of adolescent smoking, much smaller than those reasonably anticipated, would yield substantial health benefits among adults.

[3] Federal Register, Vol. 60, No. 155, August 11, 1995, p. 41362.

A reduction in teen smoking implies a considerable reduction in adult smoking, over time. Since approximately 70 percent of adult daily smokers became daily cigarette smokers by age 18, a substantial number of the youth deterred from smoking by this regulation would become nonsmoking adults. Moreover, this effect would be over and above the effects of smoking cessation programs, education, family pressures, and other public and private influences on the prevalence of smoking. While the Department estimates a probable reduction in cigarette sales of millions of dollars a year in the near term, this reduction would translate into an annual multi-billion dollar effect over the long run, as each cohort of non-smoking youth ages into non-smoking adults. FDA calculated the benefits of tobacco regulation by conservatively assuming that only one-half of the teenagers deterred from smoking would remain nonsmokers as adults.[4] That analysis, which was largely based on data from the American Cancer Society's Cancer Prevention Study II, implies that reducing the number of smoking youth by as little as 1 percent would prevent 1,200 future smoking-related deaths, gaining over 18,000 life-years, among each year's cohort of teenagers who would otherwise begin to smoke. As the projected results are proportional to the assumed effectiveness rate, this model also indicates that a 5 percent reduction in youth smoking would prevent 6,000 premature deaths, a 10 percent reduction 12,000 premature deaths and a 20 percent reduction 24,000 premature deaths among that teenage cohort. The Department believes these projections are plausible and is convinced that even very small decreases in youth tobacco consumption would yield substantial health improvements.

Benefit Estimates

The benefits of the regulation lie primarily in reducing the costs of the adverse health effects resulting from tobacco use. The CDC estimated smoking-attributable medical costs at $50 billion in 1993. The Office of Technology Assessment counted both medical costs and lost earnings to calculate $68 billion worth of smoking-related costs in 1990. For its assessment of future regulatory consequences, FDA relied on incidence-based costs of smoking, calculated over the lifetime of each year's new cohort of potential smokers. This methodology, which is described fully in the FDA economic analysis, derived values for reduced medical costs and lost wages from several earlier economic studies, particularly T.A. Hodgson, ''Cigarette Smoking and Lifetime Medical Expenditures,'' *The Milbank Quarterly*, vol. 70, No. 1, p. 91, 1992, and D.P. Rice *et al.* ''The Economic Costs of the Health Effects of Smoking, 1984, The Milbank Quarterly, vol. 64, No. 4, p. 526, 1986. In addition, FDA considered various economic analyses to support its use of a $2.5 million willingness-to-pay estimate to represent each smoking-related fatality averted. (Most notably Fisher, A. *et al.*, ''The Value of Reducing Risks of Death: A Note on New Evidence,'' Journal of Policy Analysis and Management, vol. 8, No. 1, pp. 88–100, 1989; and Viscusi, W.K., ''Fatal Tradeoffs: Public and Private Responsibilities for Risk,'' Oxford University Press, p. 24, 1992.)

As explained above, the Department now believes that the uncertainty surrounding the forthcoming responses from State enforcement agencies, industry suppliers, and adolescent users of tobacco products does not allow a precise quantitative forecast of the independent effect of this rule on adolescent tobacco use. Nevertheless, application of the benefits valuation methodology summarized above and described fully in the FDA analysis, demonstrates that even if this regulation were to achieve effectiveness rates for less than the one-tenth to one-third level believed plausible, the value of the realized benefits would reach hundreds of millions, if not billions of dollars per year. Table 1 displays these potential projections using prevent value discount rates of both 3 and 7 percent, respectively.

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[4] Ibid., p. 41360.

BENEFITS SUMMARY (Table 1)

ANNUAL ILLNESS-RELATED BENEFITS OF ALTERNATIVE EFFECTIVENESS RATES

Fraction of Teenage Cohort Deterred	Fewer Teenagers who smoke as adults * (No.)	Smoking-related deaths eventually averted (No.)	Life-Years Saved (No.)	Medical Savings ($B)	Morbidity-Related Productivity Savings ($B)	Mortality-Related Willingness-to-Pay		Total Benefits	
						Life-Yrs. Saved ($B)	Deaths Averted ($B)	Low ($B)	High ($B)
3% Discount Rate for Monetary Values									
1/3	167,000	40,100	603,600	1.8	0.6	16.4	26.4	18.8	28.8
1/5	100,000	24,100	362,100	1.1	0.4	9.9	15.9	11.4	17.4
1/10	50,000	12,000	181,100	0.5	0.2	4.9	7.9	5.6	8.6
1/20	25,000	6,000	90,500	0.3	0.1	2.5	4.0	2.9	4.4
1/100	5,000	1,200	18,100	0.10	0.02	0.50	0.80	0.62	0.92
7% Discount Rate for Monetary Values									
1/3	167,000	40,100	603,000	0.9	0.4	4.9	5.7	6.2	7.0
1/5	100,000	24,100	362,100	0.5	0.2	2.9	3.4	3.6	4.1
1/10	50,000	12,000	181,100	0.3	0.1	1.5	1.7	1.9	2.1
1/20	25,000	6,000	90,500	0.1	0.1	0.7	0.9	0.9	1.1
1/100	5,000	1,200	18,100	0.03	0.01	0.15	0.17	0.19	0.21

* Assumes 50% of adolescents who are deterred from smoking refrain as adults.

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An alternative benefits valuation methodology was presented in the economic analysis for the proposed rule. That analysis relied on the work of a Rand Corporation study (Manning, W.G. *et al.*, ''The Taxes of Sin—Do Smokers and Drinkers Pay Their Way?'' JAMA, pages 1604–1609, March 17, 1989, Vol. 261, No. 11), which estimated the 1986 net present value cost to society of smoking by comparing the excess costs of services used by smokers (i.e. employer and taxpayer share of excess medical bills, sick leave and group life insurance subsidies, lost taxes, fatalities from passive smoking, and smoking-related fires) to the taxes and premiums paid by smokers. The best estimate was a ''present value'' (discounted) cost of $0.39 per pack, under the assumption of a 5 percent discount rate applied to future costs. However, the study made no allowance for the cost of low-birthweight infants and as the Department found in the NPRM, these costs would add at least an additional 15 cents a pack.[5] Thus, the Department estimated that the net external costs born by non-smokers in 1989 exceeded 50 cents for every pack of cigarettes sold.

The Department now believes that this methodology was very conservative for valuing the benefits of smoking reductions, because it did not quantify the future benefits that would result from the expected reduction in adult smoking, and omitted all costs borne by the smokers themselves. Nevertheless, if this methodology were revised to assume that just one-half of the youth prevented from smoking were also to refrain as adults, it would predict that even a 5 percent reduction in the youth smoking rate would result in a savings of about $200 million annually to the rest of society. (According to Manning, the average smoker consumes roughly 16,300 packs over a lifetime; 25,000 fewer smokers × $.50 × 16,300 packs = $204,000,000).[6] Accordingly, a 10 percent reduction in youth smoking doubles this estimate and a 25 percent reduction raises it to $1 billion annually. Thus, despite the omission of all costs borne by the addicted smoker, this methodology confirms that even relative small reductions in adolescent tobacco use would generate substantial societal benefits.

Costs

The primary costs of complying with this regulation lie in the costs of inspection and enforcement. The Department does not have good data on the costs of enforcement because little research has been done in this area to measure costs. However, the Department does not believe these costs need to be substantial in relationship to other costs of State and local law enforcement, or to other duties faced by retail business.

The Department assumed, for purposes of analyzing costs, that the costs necessary to carry out the Model Law recommended by the Department represent the upper end of possible enforcement costs. In this scenario, a licensing apparatus must be set up, stores notified of their obligations, hearing procedures developed, a sampling design and procedure developed, both random and targeted inspections organized, fines levied, and the like. Even if an average State were to piggyback this system on top of an alcohol licensing and enforcement system, it could require a staff of one or two dozen people and an annual budget of approximately one million dollars. Across all jurisdictions, this implies costs on the order of $50 million for an effective enforcement effort. This includes all enforcement costs, including sampling and inspections.

In response to widespread concerns about inspections, and in particular to the problems of designing a sampling frame from which to select outlets to be inspected, the Department has developed additional information on these issues. It used information from the Batelle report and from cost projections of implementing a State-wide inspection system completed by CSAP's National Center for the Advancement of Prevention (''Estimating The Cost of Inspections under the Synar Amendment,'' July 1994). They analyzed the availability of data, and optimum design, for conducting random, unannounced inspections. It was concluded that in most States the most cost-effective sampling method would rely on licensing or commercial business lists, use cluster sampling rather than random sampling, and cover 300–400 outlets in the smallest half of the States and about 600 outlets in the larger States. Furthermore, it was concluded that on average, it would cost approximately $290,000 per State for an average State to develop a sampling design and conduct inspections, or about $17 million a year nationally. Some customers argued that the cost of inspections would be far lower, but these commenters did not include sampling design and selection costs.

This new estimate is broadly consistent with the original estimate that the total cost of all sampling, inspection, enforcement, and administrative costs would be about $50 million a year nationally if Model Law approaches were generally adopted. It may turn out that States are able to enforce their laws using relatively inexpensive approaches (as discussed below) in which case this $17 million estimate for the sampling and inspection functions may comprise the great majority of total costs, and the national total be closer to $25 million than to $50 million.

Regardless of what costs eventually are incurred, the Department believes that the cost of implementing this regulation should be shared by the Department and the States and therefore encourages States to use funds from the CDC's Preventive Health and Health Services Block Grant (42 U.S.C. 300w, *et seq.*), and from the Primary Prevention setaside of their SAPT Block Grants as explained earlier in this preamble. Alternatively, States could adopt a self-financing licensing and civil money penalty system or decide to raise tobacco taxes or use general fund revenues. Thus, States have a wide range of financing mechanisms available to defray their costs.

A number of commenters raised concern over the cost of using the criminal justice system—police and courts—to deal with illegal sales. The Department agrees that this would be very costly, not only in dollar terms, but also in displacing important crime-fighting activities. The Department does not recommend that States use the criminal justice system as a primary means of enforcement; instead, a system of civil money penalties and fines would almost certainly be more cost-effective.

The Department also originally estimated that retailers would incur costs on the order of $50 to $100 million annually for such functions as training staff to prevent sales to minors, with the lower range reflecting present enforcement activities. The public comments did not suggest that this estimate was flawed. However, the FDA proposed regulation's economic analysis explored retailer costs in more depth, focusing on training, and time needed to conduct identification checks on purchasers. The FDA concluded that total costs to retailers would be about $50 million annually. Accordingly, this estimate is used in this final Regulatory Impact Analysis.

[5] Federal Register, Vol. 58, No. 164, August 26, 1993, p. 45159.

[6] Manning, W.G., *et al.*, ''The Costs of Poor Health Habits, A Rand Study'', Harvard University Press, Cambridge. 1991, p. 76.

Comparison of Benefits to Costs

Based on the estimates above, the Department expects that after the several year period necessary for all or virtually all States to meet and exceed the 20 percent performance objective, net annual enforcement costs on the order of $100 million will generate annual social benefits that exceed hundreds of millions and potentially billions of dollars annually.

Because the Department was unable to make a precise quantitative estimate of the effectiveness of this regulation on youth smoking rates, it has further compared the costs and benefits using the FDA methodology assuming that much lower percentages of those deterred from smoking as youths remain nonsmokers as adults (the original analysis in Table 1 assumed that 50% of those deterred as youths would remain nonsmokers as adults). Using the original 3% discount rate, youth deterrence rates of ⅓, ⅕ and 1/10 will yield net benefits even if only 1% of those deterred as youths remain nonsmokers as adults. At the 1/20 and 1/100 youth deterrence rates, net benefits are still realized if 2% and 9% of those deterred as youths remain nonsmokers as adults, respectively. The results using a 7% discount rate are slightly higher. Youth deterrence rates of ⅓, ⅕, 1/10, 1/20, and 1/100 would yield net benefits if 1%, 2%, 3%, 6% and 28% of those deterred as youths remain nonsmokers as adults, respectively.

Distributional and Transitional Effects

The Department's cost estimates deal with the ultimate effects of smoking reductions and activities directed toward reductions. There are additional economic consequences which are not part of these calculations but which are of concern.

First, the Department believes there will be negligible adverse effects on the great majority of retail outlets. It is true that stores that currently sell tobacco products to minors will lose sales in the short run. These sales may or may not be offset by increases in sales of other items. However, with the single exception of vending machines (discussed below), the effect on most outlets will be small. There are approximately 1½ million retail sales outlets in the United States, and up to two-thirds of these sell tobacco products. (FDA estimates about one-half.) On average, tobacco products represent 5 percent of total sales in those outlets that sell tobacco. Thus, even if this rule were to achieve a one-third reduction in smoking by underage youth, the roughly $170 million near term annual shortfall (⅓ of $500 million) represents less than one-tenth of 1 percent of total sales in stores selling tobacco products. As is standard practice in estimating the economic effects of regulation, the Department assumes that there will be no loss to the economy resulting from a youth not spending $2 for a pack of cigarettes because the money will be spent on some other good or service. Considering that in many if not all cases the money not spent on tobacco will be spent on other products in the same stores, the negative economic effects on sales, costs, and profits will be negligible.

Second, the Department expects significant drops in vending-machine sales of tobacco products because of the actions that will have to be taken to prevent sales to minors from these devices. The Batelle report (Williams *et al.* estimates that about 96 percent of vending outlets sell cigarettes to minors. For the youngest minors, they are often the only easy sources of purchase. A study for the vending machine industry shows that only 23 percent of smoking youth now use vending machines often or occasionally (Response Research, Inc., ''Findings for the Study of Teenage Cigarette Smoking and Purchasing Behavior,'' June/July 1989). However, in the future this percentage would rise greatly—perhaps close to 100 percent—if enforcement eliminated other sources of illegal sales but left vending machines available to youth. Based on the research data, the Department would expect that States will face significant challenges in complying with the new law unless they impose strict controls on tobacco vending machines in locations accessible to minors.

In the original Regulatory Impact Analysis we estimated that perhaps 1,000 vending machine companies would face a loss of sales averaging about 7% of non-tax revenue. Since then, later data indicate that the economic effects will be significantly less. A long term trend towards decreased use of vending machines for cigarette sales has accelerated. According to the ''1994 State of the Industry Report'' in *Automatic Merchandiser,* August, 1994, both the projected number of cigarette vending machines and operator revenues from these machines fell by about one-fourth from 1992 to 1993 alone. According to the same source, cigarette sales are now only about 3.4% of operator revenues. Thus, the potential loss is only about half of that projected in the 1992 proposed Regulatory Impact Analysis even assuming complete elimination of vending machine sales.

A large number of commenters argued that the proposed rule represented an unfunded mandate. The Department agrees that the statute creates a financial burden for the States, albeit a burden that is very small as compared to unfunded mandates in areas such as pollution control and as compared to State expenditures taken as a whole. In response to these concerns, the Department has taken several actions. As stated earlier in this preamble, the Department is allowing States flexibility in designing enforcement strategies to reach the 20 percent goal for retail enforcement. In addition, States may, in implementing this regulation, use funds from the CDC's Preventive Health and Health Services Block Grant (42 U.S.C. 300w, *et seq*). States may also use funds from the primary prevention setaside of their SAPT Block Grant allotment under 45 CFR 124(b)(1) for sample design and inspection costs of complying with this regulation. States may not, however, use any funds from the SAPT Block Grant for any other activities related to the enforcement of their State laws. To allow States to use SAPT Block Grant funds for such activities as court costs, for example, could significantly reduce the amount of funds available for substance abuse prevention and treatment activities.

There is another cost to States in addition to costs required by this statute. Approximately 18 percent of the cost of a pack of cigarettes goes to pay State taxes. Tobacco tax losses will be offset in part by sales taxes on alternative goods purchased with the same dollars, but the net effect still could be a revenue loss because excise taxes on tobacco are higher than taxes on other consumer products. In its proposed regulations, the FDA estimated that a 50 percent reduction in the rate of tobacco consumption by youth would cause a gradual reduction in State cigarette excise tax revenues, from $31 million in the first year to $252 million in the tenth year. As discussed above, the result of the SAMHSA rule would be significantly smaller and any future lost tax revenues would diminish accordingly. To put this amount in perspective, total State and local government revenues from all sources exceed a trillion dollars a year, thousands of times this potential loss. Nonetheless, State enforcement programs involve a considerable fiscal effect that arises unavoidably if States enforce their own laws effectively and deter the illicit sale of tobacco products to minors.

Additional Alternatives

In the proposed rule the Department requested comment on several aspects of the proposed regulations. One alternative the Department considered was the application of a more stringent standard on the States, such as zero tolerance of illegal sales. However, the Department believes that risking an error which would force us to take vitally needed alcohol and drug-treatment funds from a State despite a serious enforcement effort is too dangerous at present. Hence, on an *interim* basis, and until the Department and the States gain some experience from serious State-wide efforts at enforcement, the Department will not require States to achieve this level of compliance at this time.

Second, the Department considered specifying particular enforcement measures that States must take, such as requiring that stores illegally selling to minors lose a license to sell tobacco products, or requiring local communities to enforce sales bans directly. However, the same uncertainty that would make a near 100 percent compliance objective imprudent until we have more information appears to make imposing uniform processes on all States unwise.

Third, the Department considered more stringent approaches to compliance measurement. As indicated above, random, unannounced inspections are a low-cost and highly effective method of determining which outlets violate the law. The Department considered requiring States to conduct a minimum number of inspections using youth, such as one inspection annually at 50 percent of all sales outlets. However, the Department decided that it would be premature to force a particular standard upon all States.

Paperwork Reduction Act

This final rule contains collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The title, description, and respondent description of the information collection are shown below with an estimate of the annual reporting 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. Estimates for FY 1995 and FY 1996 and thereafter are presented separately because the reporting requirements differ for these time periods.

Title: Minors' Access to Tobacco—45 CFR 96.130—FINAL RULE

Description: Data to be reported is required by 42 U.S.C. 300x–26 and will be used by the Secretary to evaluate State compliance with the statute, and the publish special analytic studies from time to time.

Description of respondents: State or local governments.

Estimated Annual Reporting Burden:

	Number of respondents	Number of responses per year	Hours per response	Total hours
FY 1995				
Annual Report:				
96.122(f)	7	1	0	[1] 0
96.130(e) (1–3)	52	1	10	[2] 520
State Plan				
96.122(g)(21)	0	0	0	[3] 0
96.130(e) (4, 5)	59	1	14	[4] 826
Total				1,346
FY 1996 and Thereafter				
Annual Report:				
96.130(e) (1–3)	59	1	10	590
State Plan:				
96.122(g) (21)	0	0	0	[3] 0
96.130(e) (4, 5)	59	1	14	826
Total				1,416

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

[2] This is the burden associated with completing the annual report narrative and Form 06B as requested in the SAPT Block Grant Application instructions and format.

[3] This section duplicates the information collection language in section 96.130(e). The burden is claimed under 96.130(e).

[4] This is the burden associated with completing the State Plan narrative as requested in the SAPT Block Grant Application instructions and format.

Under the Paperwork Reduction Act of 1995, agencies are required to provide 60-day notice in the Federal Register and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the agency;
- The accuracy of the agency's estimate of the information collection burden;
- The quality, utility, and clarity of the information to be collected; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comment on each of these issues for the information collection requirements. Comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing burden, may be sent to the agency official whose name appears in the **FOR FURTHER INFORMATION CONTACT** section above, and to Deborah Trunzo, Office of Applied Studies/SAMHSA, Room 16–105 Parklawn,

5600 Fishers Lane, Rockville, MD 20857.

We received no public comments on the estimated public reporting burden, and it remains the same as that contained in the proposed rule. We do not believe material changes made in this rule should change this burden.

Lists of Subjects in 45 CFR Part 96

Alcohol abuse, Alcoholism, Drug abuse, Tobacco.

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

Dated: December 15, 1995.

Donna E. Shalala,

Secretary.

PART 96—BLOCK GRANTS

1. The authority citation for 45 CFR Part 96, subpart L continues to read as follows:

Authority: 42 U.S.C. 330x–21 to 300x–35 and 300x–51 to 330x–64.

§ 96.122 Application content and procedures.

2. Section 96.122 is amended by adding paragraph (f)(6), redesignating paragraphs (g)(21) and (g)(22) and (g)(23) respectively and adding a new paragraph (g)(21) to read as follows:

* * * * *

(f) * * *

(6) For the first applicable fiscal year for which the State is applying for a grant, a copy of the statute enacting the law as described in § 96.130(b) and, if the State desires, a description of the activities undertaken during the previous fiscal year to enforce any law against the sale or distribution of tobacco products to minors that may have existed; and for subsequent fiscal years for which the State is applying for a grant, the annual report as required by § 96.130(e) and any amendment to the law described in § 96.130(b).

* * * * *

(g) * * *

(21) a description of the strategies to be utilized by the State for enforcing the law required by section 96.130(b);

* * * * *

§ 96.123 [Amended]

3. Section 96.123 is amended to add paragraph (a)(5) to read as follows:

(a) * * *

* * * * *

(5) The State has a law in effect making it illegal to sell or distribute tobacco products to minors as provided in § 96.130(b), will conduct annual, unannounced inspections as prescribed in § 96.130, and will enforce such law in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to individuals under the age of 18;

* * * * *

4. Section 96.130 is added to read as follows:

§ 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) The State shall annually submit to the Secretary with its application 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 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.

(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 setaside 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.

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