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Report to the Ranking Minority Member, Committee on Government Reform, House of Representatives

November 2001

SYNAR AMENDMENT IMPLEMENTATION

Quality of State Data on Reducing Youth Access to Tobacco Could Be Improved

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Accountability * Integrity * Reliability

United States General Accounting Office
Washington, DC 20548

November 7, 2001

The Honorable Henry A. Waxman
Ranking Minority Member
Committee on Government Reform
House of Representatives

Dear Mr. Waxman:

An estimated 57 million Americans currently smoke, putting themselves at risk of serious health problems, such as cancer, heart disease, and high blood pressure. Each year, over 430,000 deaths nationwide are attributable to smoking-related diseases, making tobacco use the leading preventable cause of death and disease in the United States.[1] Total spending by the Department of Health and Human Services (HHS) to prevent tobacco use and dependence is estimated at $900 million for fiscal year 2001. Tobacco use, and the resulting nicotine addiction, begins predominantly in childhood and adolescence. Every day, about 3,000 young people become regular smokers. It is estimated that one-third of these youth will die from smoking-related diseases.[2] In addition to long-term health consequences, these youth are at risk for numerous early consequences, such as a general decrease in physical fitness, early development of artery disease, and a slower rate of lung growth. If children and adolescents can be prevented from using tobacco products, however, they are likely to remain tobacco-free for the rest of their lives.[3]

In 1992, the Congress enacted legislation, referred to as the Synar amendment, to reduce the sale and distribution of tobacco products to

[1]"HHS Fact Sheet: Preventing Disease and Death From Tobacco Use", U.S. Department of Health and Human Services, Jan. 8, 2001.

[2]The National Clearinghouse for Alcohol and Drug Information, *"Tips For Teens: The Truth About Tobacco",* SAMHSA's National Clearinghouse for Alcohol and Drug Information, http://www.health.org/govpubs/phd633/ (viewed April 2, 2001).

[3]U.S. Department of Health and Human Services, *"Preventing Tobacco Use Among Young People: A Report of the Surgeon General"*, (Atlanta, Ga: U. S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 1994).

individuals under the age of 18.[4] HHS' Substance Abuse and Mental Health Services Administration (SAMHSA) is responsible for promulgating regulations and overseeing states' compliance with the Synar requirements. Synar and its regulation require states and territories to have and enforce laws that prohibit tobacco sales to minors, conduct random inspections of tobacco retail or distribution outlets[5] to estimate the level of compliance with Synar requirements, and report the results of these efforts to the Secretary of HHS. In 1996, the Food and Drug Administration (FDA) also began regulating the sale and distribution of tobacco products to individuals under the age of 18. Under the FDA regulation, the sale of tobacco products to minors was a violation of federal law that, unlike Synar, carried a civil monetary penalty against retailers. However, in March 2000 the U.S. Supreme Court ruled that FDA does not have the authority to regulate tobacco products as customarily marketed, and the program was discontinued. The Synar amendment and regulation are therefore the only federal requirements directed toward the goal of prohibiting the sale and distribution of tobacco products to minors and thereby reducing tobacco use by children and adolescents.

A key to helping evaluate the nation's progress toward this goal is credible information on the percentage of retailers that sell tobacco products to minors and on the enforcement by states of their youth tobacco access laws. In fiscal year 1997, states began reporting to SAMHSA their estimates of retailer violations and enforcement actions taken, including the assessment of penalties, against retailers who violated tobacco access laws. Because of your interest in Synar implementation and actions taken to protect children from the effects of tobacco, you asked us to (1) describe factors that can affect the quality and comparability of the retailer violation rates that states develop and (2) determine whether penalties against retailers are being used as part of enforcement strategies to reduce the sale and distribution of tobacco products to minors.

To determine the factors that affect the quality and comparability of retailer violation rates, we reviewed SAMHSA's guidance to states on developing and implementing sample design procedures and protocols for

[4]Section 1926 of the Public Health Service Act as added by the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act (P.L. 102-321, section 202).

[5]SAMHSA defines an 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."

inspecting tobacco outlets. We also examined Synar inspection information reported by the 50 states and the District of Columbia.[6] SAMHSA extracted the information from the states' Substance Abuse Prevention and Treatment (SAPT) block grant applications for federal fiscal years 1998 and 1999—the most recent data available.[7] In addition, we reviewed SAMHSA's fiscal year 1997 report to the Congress and fiscal year 1998 report to the Secretary of HHS on Synar compliance. To determine whether penalties are being used as part of states' enforcement strategies, we examined SAMHSA's summary of data on enforcement activities that states reported in their fiscal year 1999 SAPT block grant application. We also reviewed information on FDA's tobacco control program to determine how penalties against retailers were used as an enforcement tool. In addition, we reviewed the literature on evaluations of tobacco control programs and interviewed researchers and officials from SAMHSA, FDA, and eight states[8] and representatives of the National Governors' Association (NGA) and the National Association of State Alcohol and Drug Abuse Directors (NASADAD) to obtain their views on Synar implementation issues. We performed our work from June 2000 through September 2001 in accordance with generally accepted government auditing standards.

Results in Brief

Weaknesses in the states' implementation of Synar and in SAMHSA's oversight can adversely affect the quality and comparability of state-reported estimates of the percentage of retailers that violate laws prohibiting tobacco sales to minors. There are several factors that may affect the quality of the violation rates developed for fiscal years 1998 and 1999. First, in implementing their sample designs, some states used

[6]We included the District of Columbia with the 50 states in our analyses of Synar data. We refer to these 51 entities as states throughout this report.

[7]The Synar inspection and enforcement information that states report in their annual SAPT block grant applications should reflect state activities completed during the previous federal fiscal year. For example, the inspection data reported in the federal fiscal year 1999 application should be based on inspections completed by the end of federal fiscal year 1998. Our analyses in this report are primarily based on state data reported in their federal fiscal years 1998 and 1999 block grant applications. SAMHSA did not provide complete data for fiscal year 1997 because, according to SAMHSA officials, not all states submitted complete data. The states had approximately 6 months to prepare for and implement SAMHSA's sample design and inspection guidance, which was not issued until 1996.

[8]We interviewed representatives of Georgia, Idaho, Iowa, New Hampshire, New York, Tennessee, Texas, and Wyoming responsible for implementing the Synar amendment.

inaccurate and incomplete lists of over-the-counter and vending machine tobacco outlets from which to select samples for inspection, which can affect the validity of the estimated statewide violation rate. Second, in their inspection protocols, states allowed the use of minors younger than 16 as inspectors, that is, to act as purchasers of tobacco products during inspections to measure retailer compliance with tobacco access laws, even though research suggests that using such minors can artificially lower violation rates. For fiscal year 1999, 43 states reported using 14- and 15-year-olds as inspectors, and 16 of these states used them in more than 50 percent of their inspections. Five of the 16 states reported that a high percentage of their inspections—73 to 94 percent—were conducted by 14- and 15-year-olds. Third, SAMHSA approved a few states' reported violation rates even though the rates included inspection results that were invalid because the ages of the inspectors and the outcomes of the inspections were unknown. Fourth, SAMHSA relied on states to validate their own inspection results with limited verification of the accuracy of state data even though the potential reduction in a state's block grant award for not meeting annual violation-rate goals could be an incentive for states to report artificially low rates. These data quality factors, coupled with the lack of standardization in the protocols states use when inspecting outlets, can limit the comparability of retailer violation rates across states.

A little more than half the states reported for fiscal year 1999 that they used fines and suspension or revocation of retailers' licenses to penalize violators of youth tobacco access laws as part of their enforcement strategy. Other types of law enforcement actions that states reported using include the issuance of warning letters or citations. SAMHSA requires states to report evidence of actions taken to enforce state laws but does not require the use of penalties as an enforcement tool. Under FDA's discontinued tobacco control program, penalties against retailers who sold tobacco products to minors were used as an enforcement tool. SAMHSA officials said that ensuring state enforcement of youth tobacco access laws had not been their primary focus because they had been relying on FDA's enforcement activities. Research shows that enforcement strategies that include the assessment of penalties are successful at reducing minors' access to tobacco products.

We are making several recommendations to the Secretary of HHS to improve the quality and comparability of state-reported tobacco retailer violation rates. In commenting on a draft of this report, HHS generally agreed with our findings and recommendations and stated that the report is useful guidance for making changes in the direction of the Synar program.

Background

In 1996, SAMHSA issued a regulation implementing the Synar amendment. The regulation requires all 50 states, the District of Columbia, and eight insular areas[9] to (1) have in effect and enforce laws that prohibit the sale and distribution of tobacco products to people under 18 years of age, (2) conduct annual random, unannounced inspections, using a valid probability sample of outlets that are accessible to youth,[10] of all tobacco outlets within the state to estimate the percentage of retailers who do not comply with the laws, and (3) report the retailer violation rates to the Secretary of HHS in their annual SAPT block grant applications. SAMHSA requires that each state reduce its retailer violation rate to 20 percent or less by fiscal year 2003. SAMHSA and each state negotiated interim annual target rates that states are required to meet to indicate their progress toward accomplishing the 20 percent goal. Beginning in fiscal year 1997 for most states and in subsequent years for all states, the Secretary can withhold 40 percent of a state's Substance Abuse Prevention and Treatment (SAPT) block grant award if it does not comply with the rate reduction requirements. State fiscal year 2000 SAPT block grant awards ranged from about $2.5 million to $223 million.

Also in 1996, SAMHSA provided guidance to states on implementing Synar requirements. SAMHSA issued sample design[11] and inspection guidance[12] to help states comply with the Synar requirement for conducting random, unannounced inspections of tobacco outlets to estimate the statewide

[9]The eight insular areas are American Samoa, Guam, the Marshall Islands, the Federated States of Micronesia, the Commonwealth of the Northern Mariana Islands, the Republic of Palau, Puerto Rico, and the Virgin Islands. Information on these jurisdictions is not included in this report.

[10]A valid probability sample for the purpose of the Synar regulation is a random sample that includes two key elements: (1) the sample is drawn from the population of all outlets accessible to youth and (2) each outlet has a known probability of greater than zero of being selected for inspection. The sample must reflect the distribution of the outlets in the state that are accessible to youth under the age of 18, and the random inspections must be generalizable to the entire state. SAMHSA instructed states to conduct random unannounced inspections during the fiscal year with a 95-percent probability that the sampling error would be no greater than 3 percentage points.

[11]SAMHSA, *Synar Regulation: Sample Design Guidance* (Rockville, Md.: Center for Substance Abuse Prevention, Aug. 1996).

[12]SAMHSA, *Implementing the Synar Regulation: Tobacco Outlet Inspection* (Rockville, Md.: Center for Substance Abuse Prevention, Aug. 1996).

violation rate.[13] The guidance consists primarily of recommended strategies to give states flexibility in selecting a sample design and inspection protocol tailored to their particular circumstances, including state and local laws. For example, SAMHSA's inspection protocol guidance suggests that states recruit minors to attempt to purchase tobacco products when conducting inspections but gives states some flexibility regarding the ages of the minors that are used. SAMHSA's guidance requires states to develop and implement a consistent sample design from year to year and a standardized inspection procedure for all inspections so that measurements of violation rates over time are comparable across jurisdictions within a state. SAMHSA's guidance includes a Synar requirement that the states enforce their laws in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to minors. The guidance suggests that states use a variety of activities in their enforcement strategy, such as merchant education, media and community involvement, and penalties. The enforcement activities could be conducted by different agencies, such as those responsible for substance abuse prevention and treatment programs, law enforcement, and state health departments.

SAMHSA reviews state-reported information to determine whether states have complied with requirements for enforcing state laws and conducting random unannounced inspections of retail tobacco outlets. In addition to requiring states to provide evidence of their enforcement activities, SAMHSA requires states to provide their sampling methodology, inspection protocol, and tobacco outlet inspection results in their annual SAPT block grant applications. In its review, SAMHSA and its contractor[14] determine whether (1) the sample size is adequate to estimate the statewide violation rate and all tobacco outlets (including over-the-counter and vending machines) in the state have a known probability of being selected for inspection; (2) the state assessed the accuracy of lists used to identify the universe of tobacco outlets from which its sample is drawn; (3) the sample design and inspection protocols are consistently implemented each year within the state; and (4) the statewide violation

[13]SAMHSA also developed guidance documents on enforcement methods, sources of cigarettes for minors, retailer education programs, and tobacco prevention initiatives, and sponsored annual national Synar workshops and multi-state technical assistance meetings to help states with Synar implementation.

[14]SAMHSA contracts with R.O.W. Sciences, Inc., to provide analysis of the Synar sampling methodology and the results portion of the states' SAPT block grant applications.

rate is correctly calculated, meets the negotiated annual target, and shows progress toward the 20-percent goal. When data provided in the application are not sufficient to determine state compliance, SAMHSA requests additional information from the state before a final decision on state compliance is made.

SAMHSA collects the state-reported data from the SAPT block grant applications and in 1996, began storing it in an automated database. These data are used to monitor states' compliance with Synar requirements, compare state progress from year to year, and produce an annual report to the Secretary of HHS and the Congress on Synar implementation. SAMHSA also uses the data to help finalize the states' annual retailer violation rates, which are released to the public.

For fiscal years 1997 through 1999, the states' reported violation rates showed an overall increase in retailer compliance with state laws prohibiting the sale of tobacco products to minors. The median retailer violation rate declined from 40 percent in 1997[15] to 24.2 percent in 1999. Violation rates range from 7.2 percent in Florida to 72.7 percent in Louisiana for 1997 and from 4.1 percent in Maine to 46.8 percent in the District of Columbia for 1999.

SAMHSA has cited 10 states over the 3-year period for being out of compliance with Synar requirements because they did not reach their violation-rate target. The Secretary of HHS, however, has not reduced any state's SAPT block grant for noncompliance with Synar. In fiscal years 1997 and 1998, states that failed to comply with Synar requirements were not assessed a penalty because they successfully argued that there were extraordinary circumstances that hindered their inspection efforts. The states that were faced with a potential penalty by the Secretary of HHS for failing to reach their fiscal year 1999 target rates chose to commit

[15]The median violation rate in fiscal year 1997 excludes seven states that were unable to pass the required tobacco access laws because their legislatures were not scheduled to meet within the time frames covered by Synar.

additional funds to ensure compliance with the following year's violation-rate target.[16]

Implementation and Oversight Weaknesses Adversely Affect the Quality and Comparability of Retailer Violation Rates

State Synar implementation practices and SAMHSA oversight adversely affect the quality and comparability of state-reported retailer violation rates. Although SAMHSA approved states' sample designs, inspection protocols, and inspection results, the quality of the estimated statewide violation rates reported for fiscal years 1998 and 1999 is undermined because of several factors: First, some states used inaccurate and incomplete lists from which to select samples of tobacco outlets to inspect. Second, most states used minors younger than 16 to inspect tobacco outlets, and SAMHSA instructed the states to tell minors not to carry identification on inspections. Both of these protocols tend to lower the violation rate. Third, SAMHSA approved some states' violation rates even though they included invalid inspections. Fourth, SAMHSA relied on states to validate violation rates without ensuring that the accuracy of the supporting data was verified, even though a potential reduction in a state's block grant award for not complying with Synar could be an incentive to report artificially low rates. These data quality factors, coupled with the lack of standardization in the protocols states use when inspecting outlets, limit the comparability of retailer violation rates across states.

States' Use of Inaccurate Lists of Tobacco Outlets Affects the Validity of Samples for Inspection

According to SAMHSA officials, some states used inaccurate and incomplete lists to select random statistical samples of tobacco outlets to inspect, which could have affected the validity of the samples and compromised violation rates reported for fiscal years 1998 and 1999. Most states used a list-based sampling methodology in their sample design,[17] as SAMHSA recommends. When states use list-based sampling to select a

[16]To avoid a 40-percent SAPT block grant reduction for noncompliance, a provision of the fiscal year 2000 HHS Appropriations Act permitted a state to certify that it would commit state funds in an amount equal to 1 percent of that state's SAPT block grant award for each percentage point by which it missed the noncompliance sales rate (P.L. 106-113, § 218 [1999]). Under this provision, the Secretary of HHS could agree to a smaller commitment of additional funds from the seven states excluded from the fiscal year 1997 median violation-rate calculation. This discretion was not given to the Secretary of HHS in the fiscal year 2001 HHS Appropriations Act.

[17]Other sampling methods states can use include area sampling, in which outlets in randomly selected geographic areas or locations within the state are chosen; list-assisted area sampling; and census sampling, which seeks to inspect all outlets. Some states use area sampling to supplement their list-based sample.

sample of tobacco outlets for inspection, SAMHSA requires that they report evidence that they have verified the accuracy and completeness of lists for both over-the-counter and vending machine outlets. However, we found that for fiscal year 1998, 40 states reported to SAMHSA that they did not know the accuracy of the lists they were using.[18] States can use different lists to develop their population of tobacco outlets, but the accuracy and completeness of these lists vary. For example, states can use lists of state-licensed tobacco outlets, but these lists are not always updated by the responsible state agencies. Also, national and state commercial listings can be used, but they often contain many establishments that do not sell tobacco products or may identify the owners of the business but not necessarily each retail outlet. In some rural areas and Midwestern states, developing a complete list of outlets can be difficult because tobacco products are sometimes sold from individuals' homes or other places that are not known to be tobacco outlets. Comments made by several state officials indicate a need by some states for more technical assistance from SAMHSA in addressing state-specific issues—particularly sample design—that affect their compliance with Synar.

Accurately identifying the population of vending machine outlets accessible to youth in a state is also important, according to SAMHSA's fiscal year 1997 report of Synar implementation[19] and other documents, because vending machines have been a major source that children use to obtain tobacco products. In our review of the state data that SAMHSA provided from SAPT block grant applications for fiscal year 1999, we found that of the 37 states reporting that they inspected vending machine outlets, 11 did not report the population of vending machines accessible to

[18]Ten states (Alabama, Connecticut, Kansas, Maryland, Mississippi, Montana, New Mexico, Utah, Washington, and Wisconsin) reported that they knew a certain percentage of their list to be accurate. The reported accuracy of the lists for 9 of these states ranged from 70 percent to greater than 99 percent. The remaining state, New Mexico, reported that its list was about 36 percent accurate. One state, Colorado, reported that it used a list-assisted area sampling methodology, and therefore did not report on the accuracy of its list. SAMHSA officials said that this information was obtained from SAPT block grant applications and interviews with state officials. SAMHSA officials said they began requesting that states describe the accuracy and coverage of their sampling list in their fiscal year 1999 SAPT block grant applications. According to SAMHSA, 8 states did not report this information. However, SAMHSA did not provide any data on the percentage of accuracy or completeness of sampling lists for those states that did report.

[19]*Synar Regulation Implementation: Report to Congress on FFY 1997 State Compliance*, Center for Substance Abuse Prevention, Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services.

youth in their states as SAMHSA requires. (See app. I) Further, our review of a few block grant applications showed that states reported that they inspected vending machine outlets when they found them during random inspections of over-the-counter outlets. Some states have had difficulty developing accurate and complete lists of vending machine outlets, in particular, because many of the machines are privately owned and their portability makes them difficult to track. Officials we interviewed told us that over the years there has been a significant decline in vending machine tobacco outlets accessible to minors. However, an NGA representative said that vending machines are and will continue to be a source of tobacco products for minors in some states. The results of a 1999 national survey of middle school and high school students' access to cigarettes[20] show that vending machines continue to be a source of tobacco products for youth, particularly middle school students. For example, when students were asked where during the past 30 days, they bought their last pack of cigarettes, 2.7 percent of the high school students reported that their purchase was from vending machines. However, 12.9 percent of middle school students reported their last pack of cigarettes was purchased from vending machines.

SAMHSA officials told us that states need to be more aggressive in identifying tobacco outlets. An NGA study of best practices in implementing and enforcing Synar requirements notes that programs that require tobacco retailers to be licensed provide an effective source of information for identifying the outlets.[21] Not all states, however, require tobacco outlets to be licensed. SAMHSA officials said that they believe tobacco licensure programs that require the identification of every tobacco outlet and regular license renewals afford states the best opportunity to develop accurate and complete statewide lists of over-the-counter and vending machine tobacco outlets. However, in comments on a draft of this report, HHS stated that SAMHSA does not have the authority to license tobacco retailers or require states to enact legislation mandating tobacco retailer licensing or registration.

[20]*Youth Access to Cigarettes: Results from the 1999 National Tobacco Survey,* Legacy First Look Report 5, American Legacy Foundation, Oct. 2000.

[21]NGA, Health Policy Studies Division, Issue Brief, "State Best Practices in Enforcing and Implementing Synar Law and Regulations," Aug. 25, 2000. The study was based on interviews with representatives of state agencies from 18 states.

Using Younger Minors as Inspectors Can Bias Results

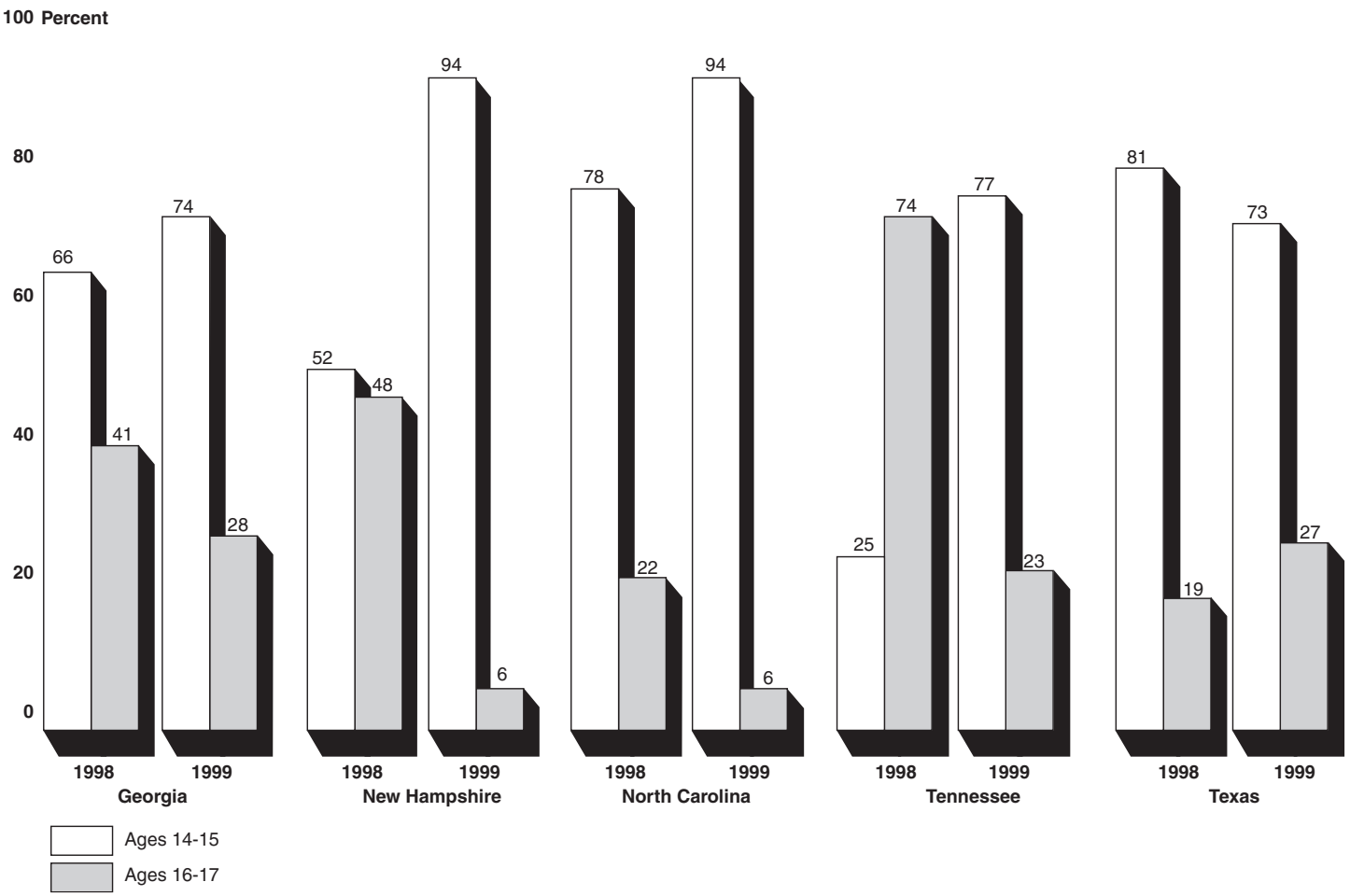
The quality of states' violation rates can be particularly affected by the age of the minors used to inspect the tobacco outlets. Research shows that minors who are younger than 16 years of age are much less successful at purchasing tobacco products than older youths.[22] Research also shows,[23] and SAMHSA officials told us that, a small difference in the age of minors can make a significant difference in a state's violation rate because the younger the minor inspectors appear, the less likely store clerks will sell them tobacco. As a result, using minors younger than 16 could bias the outcome of state inspections by lowering the violation rate. Even though SAMHSA officials are aware of the research results, they allow states to include minors younger than 16 in their inspection protocols. SAMHSA's inspection protocol guidance recommends that states use 15- and 16-year-olds as inspectors because minors younger than 15 are likely to look very young, and their appearance could discourage some retailers from selling them tobacco products. Nearly all states report using as inspectors, youth from a combination of two age cohorts, 14- and 15-year-olds and 16- and 17-year-olds.[24] For fiscal year 1999, 43 states reported using 14- and 15-year-olds as inspectors, and 16 of these states used them in more than 50 percent of their inspections. (See app. II.) Five of the 16 states (Georgia, New Hampshire, North Carolina, Tennessee, and Texas) reported the highest percentages of inspections that were conducted by 14- and 15-year-olds--73 percent to 94 percent. (See fig. 1.) Four of the 5 states also reported that a large proportion of their fiscal year 1998 inspections were conducted by 14- and 15-year-olds. Tennessee and Texas officials told us they did not purposely try to recruit large numbers of 14- and 15-year-olds. They said that they selected those minors that were willing to participate in the inspections.

[22]Joseph R. DiFranza and others, "Youth Access to Tobacco: The Effects of Age, Gender, Vending Machine Locks, and 'It is the Law' Programs," *American Journal of Public Health*, Vol. 86, No. 2 (Feb. 1996).

[23]Pamela I. Clark, and others, "Factors Associated With Tobacco Sales to Minors," *Journal of the American Medical Association,* Vol. 86, No. 2 (Aug. 9, 2000).

[24]SAMHSA requires states in their SAPT block grant applications to report by cohort the ages of minors used to conduct inspections of tobacco outlets. States are encouraged to use two age cohorts—14- and 15-year-olds, and 16- and 17-year-olds. However, SAMHSA also allows states to report inspections by minors under 12 years of age, 12 through 13 years, and 18 and older, provided states justify their use.

Figure 1: States with the Highest Percentage of Inspections Conducted by 14- and 15-Year-Olds for Fiscal Year 1999



Source: GAO analysis based on SAMHSA's summary of information reported by the 51 states in their fiscal years 1998 and 1999 SAPT block grant applications.

Inspection data supporting the violation rates for North Carolina and Tennessee show that inspections conducted by 14- and 15-year-olds resulted in lower purchase rates than inspections by 16- and 17-year-olds. For example, Tennessee reported that 14- and 15-year-old inspectors were able to purchase tobacco 16 percent of the time, whereas the 16- and 17-year-olds had a 51-percent purchase rate. New York state officials' analysis of their state inspection results for fiscal year 2000 showed that 14- and 15-year-olds were able to purchase tobacco 8 percent of the time, whereas the 16- and 17-year olds had a 21-percent purchase rate. At the time of our review, SAMHSA officials told us that they had not thoroughly examined

states' use of 14- and 15-year-old inspectors and the potential impact on retailer violation rates, but they acknowledged that this is something that will require a more comprehensive evaluation.

Another age-related inspection protocol procedure that can affect retailer violation rates is whether minor inspectors are told to carry valid identification on inspections and required to show it when asked. The research on this issue is mixed. Some research suggests that when minors are asked to show identification, retailers are less likely to sell them tobacco products. Other research suggests, and some state officials told us, that the likelihood of an illegal sale is greater if minors show identification when asked than if identification is not shown. As a result, having and showing identification when asked could potentially result in an illegal tobacco sale and a higher retailer violation rate. About half of the illegal sales in one state's inspections occurred after the minor showed proof of age.[25] Research suggests that some clerks may sell minors tobacco products because they have difficulty quickly determining an individual's age from a date-of-birth on his or her identification. According to HHS, because of safety concerns, SAMHSA recommends that minors not carry identification but answer truthfully about their age if asked by a store clerk. Research also suggests that the sex of the minor inspector can bias the inspection result. For example, when controlling for the effects of both age and sex of the inspector, one researcher found that girls were able to purchase at a 39-percent rate compared to boys who had a 28-percent purchase rate.[26] Unlike previous research, this research controlled for the effects of both age and sex.

A Few States' Violation Rates Have Included Invalid Inspection Results

SAMHSA approved four states' retailer violation rates for fiscal years 1998 and 1999 that were inaccurately calculated because they included inspections in which the ages of minor inspectors and the inspection results were not known. SAMHSA requires states to report the ages of minor inspectors in part to confirm that the ages of the inspectors are within an acceptable range. When the ages of minors used in state inspections are unknown, SAMHSA officials told us that they consider the inspections invalid, and the inspection results should be excluded from the

[25]Joseph R. DiFranza, "State and Federal Compliance With the Synar Amendment—Federal Fiscal Year 1997," *Archives of Pediatric Adolescent Medicine*, Vol. 154, No. 9 (2000), pp. 936-42.

[26]Joseph R. DiFranza and others.

violation rate computation. However, we found that SAMHSA approved and published violation rates reported by Florida, Kansas, Louisiana, and Minnesota that included inspection results in which the ages of the minor inspectors were unknown. Moreover, three of these states' violation rates included some inspections where neither the age of the minors nor the outcomes of the inspections were known. Had the invalid inspections been excluded, the violation rates for Florida, Louisiana, and Minnesota would have been higher (See table 1.) However, none of the four states would have missed its target based on the recalculated rate.

Table 1: State Violation-Rate Calculation Excluding Invalid Inspections, Fiscal Years 1998 and 1999

State and Fiscal Year	Target Rate (percentage)	Approved Violation Rate (percentage)	Rate Excluding Invalid Inspections (percentage)	Percentage Point Difference in Reported Violation Rate
Louisiana, 1998	60.00	39.00	43.37	4.37
Minnesota, 1998	26.00	28.10	27.99	-0.11
Florida, 1998	20.00	7.11	8.36	1.25
Kansas, 1999	38.00	35.00	39.76	4.76

Source: GAO analysis based on SAMHSA's summary of information reported by the 51 states in their fiscal years 1998 and 1999 SAPT block grant applications.

SAMHSA officials said that there were reasons for accepting the states' violation rates. For example, they said that they did not exclude Kansas' invalid inspections because the state provided the outcomes of the inspections. Even though Florida's retailer violation rate was based entirely on inspections in which the ages of the inspectors and the outcomes by age were unknown, SAMHSA accepted the rate because of the large number of inspections the state conducted and its low reported violation rate.

Verification of the Accuracy of State Inspection Data Was Limited

SAMHSA did not ensure that the accuracy of the data that states used to support their fiscal year 1998 and 1999 estimates of retailer violation rates was verified. SAMHSA reviewed the information states reported in their SAPT block grant applications. However, SAMHSA relied on the states to assess the quality of the data they used to develop their rates, even though the potential 40-percent reduction in a state's block grant for not meeting annual violation rate goals could provide an incentive for some states to

report artificially low violation rates. To improve their oversight, during the time of our review, SAMHSA officials completed pilot testing of their state data review protocol and began visiting states to evaluate their systems of data collection and documentation for Synar implementation. The draft review protocol SAMHSA officials said they were using includes questions about the states' sampling and inspection procedures and practices that could help in making an assessment of the quality of the data states used to develop violation rates. SAMHSA officials said that because of resource constraints, they plan to conduct these reviews approximately once every 3 to 4 years for each state.

Differences in Implementation of Synar Limit the Comparability of Retailer Violation Rates Across States

Differences in how states implement their inspection protocols, along with data quality weaknesses, limit the comparability of retailer violation rates across states. SAMHSA does not require all states to use the same set of protocols when conducting inspections of tobacco outlets. Although SAMHSA provides inspection guidelines, each state is allowed the flexibility to develop inspection protocols in keeping with its own circumstances, including restrictions in state law. Given this flexibility, there is inconsistent implementation of inspection protocols across states, which makes comparisons of retailer violation rates difficult.

States' use of different ages and sexes of minor inspectors and different criteria in determining what type of tobacco sale is a violation punishable under state law can limit comparisons of violation rates across states. For example, the ages of minor inspectors is an issue in comparisons because some states use higher proportions of younger inspectors than other states and younger minors tend to have lower purchase rates than older minors. Also, the states' use of minor boys and girls as inspectors in different proportions can limit comparisons of violation rates because females tend to have higher tobacco purchase rates than males. Another inspection procedure that can limit the comparability of violation rates between states is whether the state uses the "consummated" or the "unconsummated" buy protocol. In a consummated buy, the minor inspector completes the purchase and takes possession of the tobacco product, whereas in an unconsummated buy the minor inspector attempts or asks to purchase the tobacco product and the clerk accepts payment, but the inspector leaves without taking the product.

Some states use the unconsummated-buy protocol to protect minor inspectors, who cannot legally purchase tobacco products. For Synar inspections, if a sale is made, it is considered a successful attempt, or a violation, regardless of which protocol is used. However, according to

SAMHSA and other officials we interviewed, choice of the buy protocol can affect a state's violation rate. When the unconsummated-buy protocol is used, there could be a question of whether a violation of state law actually occurred if the minor did not take possession of the tobacco product. Some merchants are challenging in court the penalties states assess under state law for violations based on unconsummated buys. If these challenges are upheld or not resolved in those states, merchants may continue to sell tobacco products to minors because they would not expect a penalty for their actions and the states' retailer violation rates could be adversely affected. This inconsistent application of the consummated- and unconsummated-buy protocols by states and the potential effect on retailer violation rates could limit comparison of rates across states. SAMHSA's fiscal year 1999 data show that 39 states used the consummated-buy protocol and 12 states used the unconsummated-buy protocol when inspecting tobacco outlets. (See app. I.)

Comparing retailer violation rates across states could be useful in determining national progress toward the goal of reducing minors' access to tobacco products and in identifying best practices used by states that seem to be making better progress than others. Because of the lack of uniform inspection protocols across states, however, SAMHSA officials and others do not suggest making such comparisons.

Penalties Have Been Used By States as an Enforcement Tool

A little more than half the states reported in their fiscal year 1999 block grant applications that violators of youth tobacco access laws were penalized as part of the state's enforcement strategy. All states have laws that allow the use of penalties, but not all states reported that penalties were assessed, according to SAMHSA data. The states reported using a variety of enforcement actions, such as warnings, fines, and suspensions of retailers' licenses. SAMHSA officials said that in their review of state-reported information for Synar compliance, they look for evidence of active enforcement, such as the assessment of penalties, and make inquiries to state officials when the evidence is not apparent. However, SAMHSA officials also said that ensuring state enforcement of youth tobacco access laws has not been their primary focus because they were relying on FDA's enforcement activities, which included assessing monetary civil penalties against retailers. The officials said that because of the discontinuation of FDA's program, they need to examine states' evidence of active enforcement more closely to ensure that states are enforcing their youth tobacco access laws. Research shows that enforcement strategies that include the assessment of penalties are successful at reducing minors' access to tobacco products.

About Half of States Report Using Penalties in Their Enforcement Strategies

In our review of SAMHSA's summary data for fiscal year 1999, we found that 28 states reported specific evidence of having imposed penalties for violations of state youth tobacco access laws. (See app. I.) These penalties included fines against retailers and sales clerks and the suspension or revocation of retailers' licenses. Seven states reported that they took other law enforcement actions against violators, such as issuing warning letters or citations. All states have laws that allow the assessment of penalties, but not all states reported using penalties as part of their enforcement strategies. For fiscal year 1999, for example, although states have the flexibility to determine which enforcement strategies are appropriate for compliance with Synar, SAMHSA maintains that state laws are more successful in changing retailer behavior regarding selling tobacco to minors when penalties are used, and SAMHSA encourages states to use them. Florida is an example of a state that has adopted a statewide enforcement strategy that penalizes violators of its youth tobacco access laws. In its fiscal year 1998 application, Florida reported that 3 percent of the merchants who were found out-of-compliance with the state's law had their licenses revoked or suspended and 93 percent were assessed fines ranging from $250 to $1,000. SAMHSA officials said they look for evidence of active enforcement, such as the assessment of penalties, in state-reported information on Synar compliance and in some cases ask the state for an explanation when the evidence is not apparent. SAMHSA officials also said, however, that prior to the discontinuance of the FDA tobacco control program in March 2000, they relied on FDA to ensure enforcement of requirements to reduce youth access to tobacco products.

Retailers Were Assessed Monetary Penalties for Violating FDA's Tobacco Control Regulation

As a regulatory agency, FDA took an approach different from that taken by SAMHSA in prohibiting the sale of tobacco products to minors. FDA's discontinued tobacco control program focused on enforcement and required that penalties be assessed against repeat violators of FDA's regulation. FDA contracted with states to conduct inspections of tobacco outlets. FDA's contract stipulated that each state conduct at least 375 unannounced monthly compliance inspections of merchants that sold tobacco products over-the-counter, and states were instructed to re-inspect violators. FDA's goal was to have compliance checks performed throughout the entire state.[27] If an inspection resulted in a violation, the state was expected to re-inspect the establishment within 90 days and

[27]Depending on the availability of resources, some states were allowed to negotiate a lower number of checks and focus on selected sites.

continue inspections until compliance was achieved. For the first violation, the retailer would receive a warning letter. For subsequent offenses, civil monetary penalties were to be assessed ranging from $250 for a second offense to $10,000 for a fifth offense. At the time the program was discontinued, FDA had imposed a maximum penalty of $1,500 and collected an estimated total of $1 million.

Although states were allowed to use FDA contract funds for enforcement, SAMHSA officials said that states are permitted to use SAPT block grant funds for enforcement activities only if a citation is issued for a violation at the time of the inspection. States are permitted to use SAPT block grant funds to develop sample designs and conduct inspections of tobacco outlets. SAMHSA officials told us that states would need federal funds to support broader enforcement activities now that FDA's program has been discontinued. Although NGA recognizes the importance of funding enforcement, an NGA representative told us that the association is not currently advocating additional federal funding for state enforcement activities. In commenting on this report, HHS noted that state funds and tobacco settlement funds are other possible sources of funding for enforcement activities.

Officials for SAMHSA, FDA, and a state we consulted told us that they believe that without FDA's enforcement of its regulation against the sale of tobacco products to minors, some tobacco retailers will become more lax and sales to minors will increase. FDA officials also said they do not believe tobacco retailers will change their behavior without knowing that violations will result in penalties. SAMHSA officials said that they have not focused as much on state enforcement actions under Synar implementation because of their reliance on FDA to enforce its tobacco control regulation, which included penalties against retailers. They said that because FDA's program was discontinued in March 2000, they see the need to ensure that states show evidence of active enforcement of their laws.

Research suggests that enforcement strategies that incorporate inspections of all retailers followed by penalties and re-inspections are successful in reducing the availability of tobacco to minors.[28] The components of an effective enforcement strategy include an enforceable

[28]Joseph R. Difranza, "Are the Federal and State Governments Complying With the Synar Amendment?" *Archives of Pediatrics and Adolescent Medicine*, Vol. 153 (Oct. 1999).

law with penalties sufficiently severe to deter potential violators, according to the research. NGA concluded from its interviews with representatives of state agencies on best practices in enforcing Synar that the single most effective factor in reducing tobacco access to minors is the establishment of a statewide inspection and enforcement program that holds merchants and clerks accountable for their actions. Some state officials told us they believe that aggressive penalties assessed against the retailer can be very effective in changing merchant behavior. New York, for example, plans to begin confiscating merchants' lottery licenses for failure to comply with laws prohibiting the sale of tobacco products to minors.

Conclusions

The goal of the Synar amendment is to help reduce the sale of tobacco products to minors through state laws that make it illegal for retailers to sell them tobacco products. States are responsible for enacting and enforcing laws that restrict youth access to tobacco products and for reporting the progress in retailer compliance with Synar requirements. However, state implementation of Synar and SAMHSA's oversight raise concern about the quality of state estimates of the percentage of retailers that sell tobacco products to minors. These concerns center on the use of inaccurate lists of retail outlets from which to draw a sample to inspect; the use of inspection protocols among the states that could bias retailer violation rates and limit their comparability, such as the age of minor inspectors; the acceptance of violation rates that contain invalid inspection results; and the reliance on states to validate their inspection results without ensuring that the supporting data are verified. SAMHSA recently began visiting states to check their inspection practices, but more could be done to improve the quality of the inspection results and enhance the usefulness of retailer violation rates in evaluating national progress toward reducing minors' access to tobacco products.

The states have flexibility in developing strategies to help enforce their youth tobacco access laws. According to researchers and state and SAMHSA officials, assessing penalties for selling tobacco to minors, as done under FDA's program, can be an effective enforcement tool for reducing minors' access. For fiscal year 1999, a little more than half the states reported evidence of using penalties to help enforce their laws. In its oversight of state enforcement activities, SAMHSA has decided to more closely examine states' use of different enforcement strategies, including the assessment of penalties as sanctions against violators of youth tobacco access laws.

Recommendations for Executive Action

To help ensure the quality of states' estimates of tobacco retailer violation rates under the Synar amendment and to make the rates more comparable across states, we recommend that the Secretary of HHS direct the Administrator of SAMHSA to

- help states improve the validity of their samples by working more closely with them in developing ways to increase the accuracy and completeness of the lists of tobacco outlets from which they draw random samples for inspections;
- revise the inspection protocol guidance to better reflect research results, particularly regarding the ages of minor inspectors, and work with states to develop a more standardized inspection protocol consistent with state law, and more uniform implementation across states; and
- ensure that all states' retailer violation rates exclude invalid inspections, particularly those in which the ages of minors and outcomes of inspections are unknown.

Agency Comments

We obtained comments on a draft of this report from HHS. (See app. III for agency comments.) In general, HHS agreed with our findings and recommendations and found our report to be useful guidance for future changes in Synar implementation. HHS disagreed with our recommendation that SAMHSA require more standardization in inspection protocol development consistent with state laws and more uniform implementation across states. HHS stated that this action would accomplish very little in the way of meaningful comparisons of violation rates across states without federal legislation requiring states to modify their practices and possibly lead to changes in state laws pertaining to inspection protocols. We believe, however, that federal legislation may not be necessary. There are consistencies that currently exist in inspection protocols among many of the states, such as in the ages of minors used to conduct inspections. Identifying other key inspection protocols that states may be able to adopt, such as whether minor inspectors should carry identification, would provide a core group of protocols that could enhance comparisons of retailer violation rates across states. In light of HHS' comment, however, we revised our recommendation to have the Secretary of HHS direct SAMHSA to collaborate with states in developing more standardization in protocols and uniform implementation across states. HHS officials also provided comments intended to increase the report's accuracy. Where appropriate, we have incorporated HHS' suggested changes and technical comments in this report.

As we agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days from the date of this letter. We will then send copies to others who are interested and make copies available to others who request them.

If you or your staff have any questions about this report, please contact me at (202) 512-7119 or James O. McClyde at (202) 512-7152. Darryl W. Joyce, Paul T. Wagner, Jr., and Arthur J. Kendall made key contributions to this report.

Sincerely yours,

Janet Heinrich
Director, Health Care—Public Health Issues

Appendix I: Selected Characteristics of States' Synar Implementation Strategies Reported for Fiscal Year 1999

State	Did not report the population of vending machines	Inspected vending machines	Used the unconsummated-buy protocol	Type of law enforcement action taken
Alabama		X		Fines
Alaska		X		License suspensions
Arizona		X	X	[e]
Arkansas	X[a]	X		License suspensions, warnings
California		d		Fines
Colorado	X[b]	X		Fines, warnings
Connecticut		X	X	Fines, warnings
Delaware		[d]		Fines
District of Columbia			X	Warnings
Florida		X		License revocations and suspensions, fines, warnings
Georgia		X		[e]
Hawaii		[d]		Fines, citations
Idaho		X		Citations
Illinois		X	X	License revocations, fines, citations, warnings
Indiana		[d]	X	Warnings and arrest tickets
Iowa		[d]		[e]
Kansas		[d]		Fines
Kentucky	X[a]	X		Fines, citations
Louisiana	X[a]	X		Citations
Maine		[d]		[e]
Maryland	X[a]	X	X	Citations
Massachusetts		X		Fines, citations
Michigan		X	X	[e]
Minnesota		X		[e]
Mississippi		[d]		Warnings
Missouri				Fines
Montana		X		Fines
Nebraska	X[a]	X		Fines
Nevada		X		Fines
New Hampshire		X	X	[e]
New Jersey		X		Fines, summonses, warnings
New Mexico		[c]	X	Fines, citations
New York	X[a]	X		License suspensions
North Carolina		X		Defendants charged under misdemeanor statute

State	Did not report the population of vending machines	Inspected vending machines	Used the unconsummated-buy protocol	Type of law enforcement action taken
North Dakota		X		License suspensions, fines warnings
Ohio	X[a]	X		Fines, warnings
Oklahoma		X		Fines, citations
Oregon		[d]		Fines, citations
Pennsylvania	X[a]	X		[e]
Rhode Island		X		Fines, warnings, citations
South Carolina		X		Fines
South Dakota		X		Fines, warnings
Tennessee		X	X	Fines, citations
Texas		X	X	Citations, warnings
Utah		[d]		[e]
Vermont		[d]		[e]
Virginia	X[c]	X	X	[e]
Washington		[d]		[e]
West Virginia		X		[e]
Wisconsin	X[c]	X		[e]
Wyoming		X		[e]
Total	**11**	**37**	**12**	

[a]State did not report the specific number of vending machine outlets because its (1) lists of businesses or state-licensed outlets did not specify vending machines from other types of outlets or (2) the number of vending machine outlets was unknown because the state licenses vending machine companies or owners.

[b]Because state used area sampling, reporting the population of vending machines was not necessary.

[c]Information not provided.

[d]State laws or regulations either banned tobacco vending machines or restricted youth access. According to SAMHSA officials, states that have laws that restrict tobacco vending machines are not required to inspect them.

[e]Specific law enforcement action taken was not reported.

Source: Summary of information SAMHSA extracted from states' fiscal year 1999 SAPT block grant applications and SAMHSA's comments on a draft of this report.

Appendix II: Percentage of State Tobacco Outlet Inspections Conducted by 14- and 15-Year-Olds, Fiscal Year 1999

States With Greater Than 50 Percent of Inspections by 14- and 15-Year-Olds (Percentage)			
New Hampshire	94	Maryland	60
North Carolina	94	Washington[a]	59
Tennessee	77	Pennsylvania	54
Georgia	74	West Virginia	54
Texas	73	Arkansas	53
Delaware	70	Alabama	53
Indiana	66	Oklahoma	53
Nebraska	63	California	52
States With Less Than 50 Percent of Inspections by 14- and 15-Year-Olds			
Virginia	49	Alaska	32
South Carolina	49	Illinois	30
Colorado	47	Louisiana	28
Florida	46	Ohio	28
Wisconsin	46	Kentucky	27
Oregon	43	Missouri	24
New York	43	Iowa	21
New Mexico	43	Minnesota	19
Maine	42	Utah	13
Rhode Island	42	Nevada[a]	6
New Jersey	42	Arizona	0
Massachusetts	42	Connecticut	0
Hawaii	40	District of Columbia	0
Mississippi	35	Idaho	0
Montana	34	North Dakota	0
Kansas[a]	32	South Dakota	0
Michigan	30	Vermont	0
		Wyoming	0

Note: Table is based on 51 states that reported the ages of minor inspectors. Three states reported using minors younger than 14.

[a]Percentage excludes inspections in which the ages of minor inspectors were not reported in SAPT block grant applications.

Source: SAMHSA's summary of information states reported in their fiscal year 1999 SAPT block grant applications.

Appendix III: Comments From the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of Inspector General

Washington, D.C. 20201

SEP 26 2001

Ms. Janet Heinrich
Director, Health Care--Public
Health Issues
United States General
Accounting Office
Washington, D.C. 20548

Dear Ms. Heinrich:

Enclosed are the Department's comments on your draft report, "Synar Amendment Implementation: Quality of State Data on Reducing Youth Access to Tobacco Could Be Improved." The comments present the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

The Department also provided extensive technical comments directly to your staff.

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely,

Janet Rehnquist
Inspector General

The Office of Inspector General (OIG) is transmitting the Department's response to this draft report in our capacity as the Department's designated focal point and coordinator for General Accounting Office reports. The OIG has not conducted an independent assessment of these comments and therefore expresses no opinion on them.

Comments of the Department of Health and Human Services on the U.S. General Accounting Office Draft Report, "*Synar Amendment Implementation: Quality of State Data on Reducing Youth Access to Tobacco Could Be Improved*"

General Comments

Following a detailed review, the Department of Health and Human Services finds the General Accounting Office's (GAO) report to be useful guidance for future changes in program direction. We offer the following comments that we believe would increase the report's accuracy.

The GAO report describes in detail the issue of accurate measurement of State success in reducing retailer violations of tobacco access laws for youths. In discussing accurate measurement, it is usually necessary to first define the standard of performance being measured. However, the report does not explicitly define this standard. With regard to the discussion about the age of inspectors as an influence on inspection outcomes, two possible standards of measurement are to find the largest possible number of violations of tobacco sales to minors laws, or measure the likelihood that a typical underage smoker will be able to access tobacco through retail sources.

The GAO report appears to focus on the first standard. For example on page 8 the report states, ". . . the quality of the estimated statewide violation rates reported for fiscal years 1998 and 1999 is undermined because of several factors:. . . .Second, most states used minors younger than age 16 to inspect tobacco outlets, ..." On page 11, the report notes that, "Research shows that minors who are younger than 16 years of age are much less successful at purchasing tobacco products than older youths. . . .As a result, using minors younger than age 16 could bias the outcome of state inspections by lowering the violation rate." If finding the largest number of violators is the standard, then the report's emphasis on the age of 16 needs explanation since increased violation rates may be achieved through the exclusive use of 17-year-old inspectors. The Department's Substance Abuse and Mental Health Services Administration (SAMHSA) does not recommend this approach because it does not measure retailer violation rates or youth access as they occur under real-world conditions. Rather, this approach seeks to identify and penalize a maximum number of violators.

The SAMHSA's intent is to accurately measure the likelihood that a typical underage smoker will be able to access tobacco through retail sources. If this is the standard, then it is important that youth in a range of ages be included in inspections, because some youth under the age of 16 both smoke and attempt to purchase cigarettes. In fact, numerous studies show that minors of very young age are able to access cigarettes through retail sources (Naum, Yarian and McKenna, Journal of the American Osteopathic Association, pages 663-665, November 1995). Thus, SAMHSA allows States to use a range of inspector ages.

The report addresses the issue of comparability between States in the results of their Synar surveys. While interstate comparisons would be interesting, the Department decided early in the process of developing the Synar program that comparability between States was not feasible due

to differences in numerous areas, including State laws that impact inspection protocols and confound across-State comparisons. Among these confounding factors were differences in laws concerning: youth possession of tobacco; ages of cooperating individuals; legal ages of purchase; and law enforcement involvement in inspections. Instead, the Department emphasized the comparability of each State's survey results from year to year. This allowed the Department to assess the measure most emphasized in the Synar law and regulation: the reduction of each State's retailer violation rate to their annual targeted rate, and ultimately to 20 percent or less by Fiscal Year (FY) 2003. No reference to this approach, or analysis of it, was provided in GAO's report.

While some of SAMHSA's guidance documents are referenced, the report does not give a complete picture of the broad range of SAMHSA's technical support to States in implementing the Synar regulation. The SAMHSA has developed a series of guidance documents on topics including: sampling methods; inspection procedures; effective enforcement methods; sources of cigarettes for minors; retailer education programs; and tobacco prevention initiatives. In addition, SAMHSA has: held annual national Synar workshops; held several multi-State technical assistance meetings per year; and prepared several data analysis documents in support of State implementation of the Synar regulation. Individualized State technical assistance has also been provided in the topic areas where a State has requested help. These documents, meetings, and individualized assistance visits are designed to work together as a comprehensive approach. They cover the range of issues States are confronting in their implementation of the Synar requirements with the goal of reducing noncompliance rates through a collaborative relationship between SAMHSA and the States.

The Department believes that an audit would assess a program's achievement of its major outcomes. However, the report does not adequately address what the Department believes is the most significant measure by which the Synar program should be assessed: Whether retail sales rates of tobacco to youth and concurrent youth access to tobacco have declined. On page 8, the report notes that, "The median retailer violation rate declined from 40 percent in 1997 to 24.2 percent in 1999." However, this fact is not brought forward into the conclusions of the report. Also, despite ever-increasing rigor in the review of State Synar survey reports, this median rate has continued to decrease, to 22.4 percent in FY 2000. Even if reported State retailer violation rates were not 100 percent accurate, the pattern of decline in median rates indicates that youth access to tobacco through retail sources has been significantly reduced. This decline is due, at least in part, to the combined and cooperative efforts of the Department and the States in implementing the Synar requirements.

GAO Recommendation

To help ensure the quality of states' estimates of tobacco retailer violation rates under the Synar amendment and to make the rates more comparable across states, we recommend that the Secretary of HHS directs the Administrator of SAMHSA to

- help states improve the validity of their samples by working more closely with

states in developing ways to increase the accuracy and completeness of the lists of tobacco outlets they use to draw random samples for inspections;

Department Comment

The Department concurs with this recommendation. The accuracy and completeness of retail outlet lists have been an ongoing concern in SAMHSA's Center for Substance Abuse Prevention reviews of States' Synar reports. The accuracy and completeness of these reports becomes even more important as target retailer violation rates fall to 20 percent and below.

On page 10, second sentence of the second paragraph, the GAO report states that, "An NGA study of best practices in implementing and enforcing Synar requirements notes that programs that require tobacco retailers to be licensed provide an effective source of information for identifying the outlets." However, not all States require tobacco outlets to be licensed, and SAMHSA does not have authority to license federally or to require State legislation for tobacco retailer licensing or registration.

It should be noted that the Department's Food and Drug Administration (FDA) established retailer list development and maintenance as a major priority in regulating the sale of tobacco products to minors. In order to enforce the Federal regulation prohibiting the sale of cigarettes and smokeless tobacco products to minors, FDA created and maintained a national list of tobacco retailers from which FDA would select retailers for unannounced compliance checks during which a minor, accompanied by a commissioned officer, would attempt to purchase cigarettes or smokeless tobacco. (Certain types of retailers, for example convenience stores, go into and out of business quickly. Therefore, it was necessary to continuously update and maintain the national retailer list.) With regard to SAMHSA establishing such a national retailer list, it would have to be determined whether SAMHSA has the authority to create and maintain such a list.

Furthermore, GAO's report suggests that States would benefit from additional resources as they attempt to improve their tobacco retailer lists. Since the report is based on survey data through FY 1999, the Department also refers to the following activities conducted by SAMHSA which have helped States to improve the quality of their lists in FY 2000 and FY 2001. These activities include: requiring States to report and justify the accuracy and completeness of their lists; including improvement of sample lists as a topic at technical assistance workshops; helping to assess the validity of lists through site visits to States; and requiring some States to do limited area sampling to assess list accuracy.

Additionally, SAMHSA revised their sampling guidance document (to be released shortly), strengthening their recommendation that States crosscheck the tobacco retailer lists from which they derive their samples by visually inspecting or canvassing selected retail inspection areas.

3

GAO Recommendation

- revise the inspection protocol guidance to better reflect research results, particularly regarding the ages of minor inspectors and require more standardization in inspection protocol development consistent with state law and more uniform implementation across states; and

Department Comment

The Department concurs with the first part of this recommendation which reads, ". . . revise the inspection protocol guidance to better reflect research results, particularly regarding the ages of minor inspectors. . . ." The minimum age of minor inspectors was increased to 14 years in FY 1999, and Substance Abuse Prevention and Treatment Block Grant software was modified to reflect this change. Furthermore, research indicates that the largest increase in the ability of youth to purchase tobacco occurs between the 14 and 15-year-old age groups (Forster, Hourigan, and McGovern, Journal of Preventive Medicine, 21, pages 320-328, 1992). As such, since 1996, SAMHSA has recommended that States use youth inspectors who are 15 and 16-years-old, which is also consistent with FDA's inspector ages.

The last part of this recommendation, which reads, ". . . and require more standardization in inspection protocol development consistent with state law and more uniform implementation across states;. . . ." would entail legislation requiring States to modify their practices, and possibly, amending current State laws governing inspection protocols. Currently, State laws vary a great deal in their standards for implementing the Synar requirements, including how inspections will be accomplished, and which State entity is responsible for Synar implementation. As such, in the absence of legislation, we believe that revised standardized protocol guidance and consistent implementation across States will have a minimal impact on the issues identified by GAO.

GAO Recommendation

- ensure that all states' retailer violation rates exclude invalid inspections, particularly those where the ages of minors and outcomes of inspections are unknown.

Department Comment

The Department concurs with this recommendation. The SAMHSA has already implemented this standard as of FY 2000. The SAMHSA has only approved applications where the outcomes of the inspections are known, and where the numbers of inspections by inspector age matched the total numbers of inspections completed, and which were used to calculate the retailer violation rate.

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