IMPACT OF INCLUDING ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS) IN A STATE INSPECTION PROTOCOL ON STATE RETAIL VIOLATION RATE IN THE SYNAR YOUTH TOBACCO PREVENTION PROGRAM

by

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Abstract

Introduction and Background: The Synar regulation (45 C.F.R. § 96.130) is a Federal regulation and program administered by the States that requires enforcement to prevent the sale of tobacco products to those under the legal age of sale. Penalties are given to States that exceed a federally mandated retail violation rate (RVR). Tobacco use is changing with youth use of cigarette smoking decreasing and use of Electronic Nicotine Delivery Systems (ENDS) is increasing. There is a high economic and personal cost of ENDS use, although the full range of long-term negative outcomes of ENDS use are yet to be quantified. States are beginning to include ENDS in their Synar inspections and may worry that inclusion of ENDS may reduce their RVR compliance.

Methods: RVRs were collected and listed from each of the 50 States and District of Columbia through manually reviewing each State’s 2020 RVR. Retail Violation Rate was used to compare with inspection of ENDS, presence of a high prevalence of ENDS use in the environment, and presence of regulations of ENDS.

Data was collected for State RVR, Retail Availability of ENDS, ENDS Use in State, Use of Under 21 Year Old Inspectors, ENDS Included in Inspections, Inspectors Carry ID, Any Change in Law Regarding Inspections, and Other Changes in State Law. RVRs were dichotomized into categories of high RVR and low RVR and analysis was conducted.

Results: Inclusion of ENDS in Synar inspections was not found to have significant impact on RVR. High retail availability and youth inspectors carrying identification had a low association with a State having a high RVR. High ENDS use in a State, changes in state law around
inspections, other state law changes, and use of inspectors over the age of 18 were not found to be related to high RVR. *Discussion:* A State should not be concerned that including ENDS in its Synar inspection protocol will have impact on State compliance with the requirements of the Federal Synar Regulation. These results can allow States to best target prevention resources based on the findings of which variables influence RVR. Best practices to account for these variables can be identified and targeted policies and regulations can be implemented.

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Chapter 1: Introduction

Tobacco use amongst youth in the United States is an immediate concern to our nation’s health. The Centers for Disease Control and Prevention (CDC) notes that if cigarette smoking continues at the current rate among youth in this country, “5.6 million of today’s Americans younger than 18 will die early from a smoking-related illness. That’s about 1 of every 13 Americans aged 17 years or younger who are alive today.” The CDC further notes that “each day in the U.S., about 1,600 youth smoke their first cigarette and nearly 200 youth start smoking every day.”

The landscape on tobacco use has changed, particularly in methods of use and usage patterns. The significance of usage has grown more alarming in terms of U.S. dollars spent and the negative impact of use on the personal health of Americans. The Synar program was initiated to combat youth tobacco usage, and requires a many specific annual reporting requirements. The Synar Amendment has been amended and clarified since its inception in 1992.

While youth tobacco use remains high in the United States, the methods of use have changed in recent years. Tobacco product usage has changed from traditional combustible cigarettes to ENDS over the past decade. From 2011 to 2019, current (past 30 day) cigarette smoking went down among middle and high school students. About 2 out of every 100 middle school students (2.3%) reported in 2019 that they smoked cigarettes in the past 30 days—a decrease from 4.3% in 2011. Additionally, about 6 of every 100 high school students
(5.8%) reported in 2019 that they smoked cigarettes in the past 30 days—a decrease from 15.8% in 2011.

However, current (past 30 day) use of e-cigarettes increased among middle and high school students from 2011 to 2019. In fact, about 1 of every 10 middle school students (10.5%) reported in 2019 that they used electronic cigarettes in the past 30 days—an increase from 0.6% in 2011. More than 1 of every 4 high school students (27.5%) reported in 2019 that they used electronic cigarettes in the past 30 days, marking an increase from 1.5% in 2011.

Tobacco product utilization is significant due to the high economic (dollars spent) and personal cost (health quality and length) of tobacco use. The economic cost of tobacco utilization includes healthcare spending, prevention advertising, and lost productivity. Personal cost includes the health impact of exposure, illness, and death. Tobacco is the nation’s leading cause of preventable death and costs the United States billions of dollars every year. E-cigarettes have been the most commonly used tobacco products among youth since 2014. It is important to target the most frequently used tobacco products for youth in undercover inspections so that such inspections can be most effective in sales prevention. Most tobacco product use is started and established primarily during adolescence, so it is essential to focus tobacco prevention efforts on this population.

In July 1992, Congress enacted the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act (Pub. L. 102-321). This Act included an amendment (Section 1926, codified at 42 U.S.C. § 300x-26) aimed at decreasing youth access to tobacco. The Synar Amendment and its implementing regulation requires States to enforce laws prohibiting the
sale and distribution of tobacco products to individuals under the legal age of sale (18 years old at the time data was collected for this study, and 21 years old as of December 20, 2019). This amendment was named for its sponsor, Congressman Michael Synar of Oklahoma, and originally required that all States, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and six Pacific jurisdictions enact and enforce laws prohibiting the sale or distribution of tobacco products to individuals under the age of 18.

States must comply with the Synar Amendment in order to receive their full Substance Abuse Prevention and Treatment Block Grant (SABG) awards administered by the Substance Abuse and Mental Health Administration (SAMHSA). At the time of the Synar Amendment’s passage, state enforcement of youth tobacco prevention laws was low and 76% of test purchases by minors resulted in sales.

The original Synar Amendment and corresponding regulations from SAMHSA required States and Territories to address State failure to enforce tobacco sale age requirements and high sales to minors. Congress sought to address the issue through Amendment by enforcing laws prohibiting any manufacturer, retailer, or distributor of tobacco products from selling or distributing such products to any individual younger than age 18.

Every year each State must submit an Annual Synar Report (ASR) detailing State activities to enforce their laws. Among other variables (including narrative sections that note descriptive process of inspections and challenges that a State may encounter) this report details what tobacco products youth are asking for in inspections. Please refer to Appendix A for a blank ASR.
The Synar Amendment requires the States to conduct (and report on) annual random, unannounced inspections in a way that provides a valid probability sample of outlets accessible to minors. These inspections involve sending a youth inspector into a retail outlet to attempt to buy a tobacco product. Furthermore, since Federal Fiscal Year (FFY) 2003, a 20 percent Retail Violation Rate (RVR) threshold was established for States and U.S. jurisdictions.\(^8\) Retail Violation Rate refers to the number of violations over all inspections that a State has conducted over a FFY. Retail Violation Rate is presented as a percentage. The Retail Violation Rate (RVR) represents the total number of buys (numerator) over the total number of completed inspections (denominator) within the Federal Fiscal year, converted into a percentage. Exceeding the 20% threshold (within a three percent margin of error) results in penalties to the State.\(^8\)

From its inception to midway through Federal Fiscal Year 2020 (October 1, 2019 through September 30, 2020), the Synar Amendment and its corresponding regulation (45 C.F.R. § 96.130) prevented the sale of tobacco products to those under 18, with the age limit being able to vary by State.\(^10\) On December 20, 2019, the legislation raising the federal minimum age for sale of tobacco products from 18 to 21 years became law (21 U.S.C. § 387f(d)(5)).

This minimum age went into effect immediately and applied across all States to all retail establishments and persons with no exceptions. Furthermore, this legislation applies to a retailer selling any tobacco product (including cigarettes, cigars, and e-cigarettes) to anyone under 21. There is a three-year transition period outlined for the State to comply with the statute to raising the federal minimum age for sale of tobacco products from 18 to 21 years,
referred to as “Tobacco 21.” This revision did not address use of Electronic Nicotine Delivery Systems (ENDS).

While the Synar program is authorized through a Federal statute, it is an unfunded mandate that allows States to have discretion in how they conduct their Synar sample, choose how to conduct their inspections, and enforcement. This allows variations between States in sampling techniques (census or random sample) and inspection protocol (such as consummated or unconsummated buy, and requirement for a youth inspector to show identification, and product requested).

However, the requirements noted in the statute and regulation must be met for the State to receive its full SABG award. Inspections, where an undercover youth attempts to buy a tobacco product at a tobacco retailer, must be initiated by an underage youth pursuant to the State’s law.

Inspections that are not completed due to safety, closures, or inaccessibility are not included. The RVR must remain below 20% for a State to maintain compliance with the Federal target. States that do not comply with the Synar requirements are subject to a penalty of 40 percent of their Federal SABG funding. However, since 2000 Congress has provided an alternative penalty mechanism by which a State can avoid the 40-percent reduction in its SABG if the State stipulates that it will spend its own funds to improve compliance with the law.

This alternative penalty is outlined in Section 218 of the 2000 Further Consolidated Appropriations Act (Pub. L. 106-113) and provides a penalty alternative for States not meeting the Synar target rate. This alternative requires a State to commit new State funds for tobacco
access compliance activities, supplement and not supplant existing funds for tobacco prevention and compliance activities and provide reports to the Secretary of the Department of Health and Human Services on all State resources for prevention and compliance activities.8

In FFY 2020 the penalty was altered to a 10 percent penalty of the SABG (Pub. L. 116-94). States found out of compliance with their RVR must now submit a corrective action plan to the Assistant Secretary for Mental Health and Substance Use within 90 days of receipt of notice informing them that they are not in compliance with the Synar regulations, which outlines strategies they will take to reduce the RVR to 20 percent or less.8

The revised alternate penalty in FFY 2020 allows a State the same obligations including the requirement to implement a corrective action plan, though the State must account for the 10% of the total rather than the previously noted 40%.

The ASR also requires States to attach data of all inspections in Excel to their report, including age and gender breakdown of youth inspectors, and outcome of inspection. These data include buy frequencies and buy rate by type of retail outlet, age, and gender. The retailer types collected include gas stations, tobacco store, restaurant, hotel, grocery store, drug store, other, missing, and invalid. It is up to the State to determine classification, for example, a “convenience store” without gas may be considered as a grocery store or other.

A youth access law or regulatory policy can be noted via information provided in the ASR (available in Appendix A). The State adds a copy of any youth tobacco access law to its ASR submission. In addition, the ASR allows for a description of plans for law enforcement efforts to enforce youth tobacco access laws, activities that support law enforcement efforts to enforce
youth tobacco access laws, and any anticipated changes in youth tobacco access legislation or
regulation in the State.

The ASR also collects other policy and State regulation information in its Appendix C
Inspection Protocol, such as whether the buy is consummated or not, if the State uses
inspectors over age 18, if adult inspectors enter the outlet with the youth, if the youth is
compensated, whether the youth carries ID, and legal and procedural requirements. This
information can be used to determine whether States that have regulatory policies on ENDS,
utilize inspectors over age 18, or have inspectors carrying ID has an association with RVR.

Data in the ASR include weighted and unweighted Retailer Violation Rate, standard
error, right-sided 95% confidence interval (one sided confidence interval), two-sided 95%
confidence interval, design effect, weighted and unweighted accuracy rate, and weighted
completion rate. Sample size information such as effective sample size, target (Minimum)
sample size, original sample size, eligible sample size, and overall sampling rate are also
included.

Data from the ASR can be utilized for research purposes including answering the overall
question of this study: whether a youth inspector requesting ENDS (instead of a different
product) would increase the RVR for that State. A State may fear adding a product to Synar
inspections that may raise their RVR, causing a state to be out of compliance with the 20% limit
on violations and lead them not to receive their full SABG funding. The Substance Abuse Block
Grant is relied on by States to fund substance use services for the upcoming year. The SABG
helps plan, implement, and evaluate activities that prevent and treat substance abuse. This
study seeks to determine whether ENDS inclusion in State Synar inspections impacts RVR. This study also examines the impact of ENDS on RVR by establishing whether States that have high ENDS use and retail availability also have higher RVRs.

The impact of increased youth use of ENDS on RVR (and therefore compliance) with SAMHSA Synar requirements is not known. Prior to my research, it was unclear whether higher youth ENDS use adversely impacts RVR because States do not uniformly ask for ENDS in Synar inspections. This dissertation addresses the impact on RVR of ENDS and other factors based on information provided by the ASR.

Additional information provided in the ASR can help assess whether presence of tobacco support activities such as presence of youth access laws (such as a law providing a criminal vs. civil fine to store owners or clerks), use of inspectors over the age of 18, and whether an inspector carries identification have any impact on the RVR. Such additional information can help inform changes to a State’s RVR and compare any variation to that of including ENDS.

One can also incorporate data concerning tobacco in the environment such as generally high ENDS use in a State or high retail availability of ENDS in a locality. These data are collected by the Center for Disease Control and Prevention’s (CDC) Youth Risk Behavior Surveillance System (YRBSS).
References


Chapter 2: Literature Review

The Need for Study on ENDS Impact on RVR

A substantial body of research on ENDS use has emerged in recent years. This emergent research that has shown increased usage of ENDS. However, State and local regulation and policy development regarding ENDS remains in the early stages.\(^\text{11}\) Research of inclusion of ENDS in tobacco inspections is in its infancy, and there is no data available on ENDS in Synar inspections.

A study by Hongying Dai in 2020 analyzed the Food and Drug Administration (FDA) compliance inspection database for data on ENDS in (non-Synar) inspections between 2016 (when the FDA started to inspect for e-cigarettes) and 2018.\(^\text{12}\) Dai determined that e-cigarettes, cigars, cigarettes, and smokeless accounted for 4673 (20.0%), 9439 (40.4%), 8303 (35.6%), and 937 (4.0%) of total warning letters sent from the FDA\(^\text{12}\) during this time period. Dai’s study illustrated an impact of including ENDS in inspections by a significant number of warning letters sent.

However, Dai’s study was not able to compare the violation rates across tobacco products because the number of tobacco products inspected in compliance checks were not reported in the data. My study on ENDS was able to review the presence of a relationship between ENDS regulation regarding youth inspections and RVR. This is because Synar inspections reported in the ASR list the tobacco products each State inspects for.
Some States choose not to inspect for ENDS and regularly including ENDS in Synar inspections is a relatively new occurrence. States that inspect for ENDS and their RVRs are examined in this dissertation’s results and noted in Figure 4. The FDA began including ENDS as an option for purchase in compliance inspections in 2016, and the compliance requirements for ENDS manufacturers regarding sales to minors was not made until June of 2019. Since 2016, FDA has issued more than 8,000 warning letters to retailers — both online and in brick-and-mortar retail stores — for sales of ENDS and their components to minors. The FDA including ENDS in compliance inspections and alerting retailers of such allowed States to more regularly include such products in State specific Synar inspections.

The “Deeming Rule”

In August of 2016, ENDS were deemed as subject to the authority of the U.S. Food and Drug Administration (FDA) and regulated as tobacco products under federal law (81 FR 28974). This “deeming rule” meant that “laws prohibiting sales to minors, requiring ID checks, restricting vending machine purchases, and mandating health warning labels that currently apply to cigarettes, smokeless tobacco, and other "conventional tobacco products" will extend to ENDS.” This deeming rule provided a set definition for ENDS to be incorporated into existing FDA regulatory policy regarding sales to minors. This regulatory action allowed ENDS to be commonly defined as a product that could be added as a group to inspections, local regulations, and preventative action. Since stakeholders such as States, advocacy groups, and legislators now had a commonly defined set list of products, they could gauge purchase of these products by minors in inspections, usage by demographic groups, and regulations.
The FDA noted that this deeming rule did not have preemptive effect, meaning State and local governments retain authority to enact additional restrictions on the distribution, sale, and use of ENDS. The deeming rule allowed State and local governments the ability to determine whether ENDS should be restricted in the same manner as other tobacco products by defining what that product was.

**Safety of ENDS and Variations in Regulation**

ENDS studies have come to different conclusions concerning ENDS safety and efficacy as quit tools. Study has suggested that ENDS may contain toxicants and long-term health effects of such toxicants are unknown. However, some previous experimental and observational studies have found that ENDS may be effective quit tools, while other studies contradict this conclusion.

This contradiction allows for discrepancies in ENDS regulation between jurisdictions where policies are dependent on the political will and interpretation of evidence. For example, some States such as Alaska, Idaho, Kansas, and Wisconsin first put prohibitions on ENDS sales to minors in 2012, while Ohio did not until 2022. States with earlier prohibitions on ENDS sales have varying outreach compared with States with fewer or no prohibitions. This is evident where education and window clings are quickly provided to retailers in some States and others where State level education is not available.
In fact, opinion of ENDS risks in the U.S. has shifted in adult smokers between 2010 and 2017. In 2010 over 70% of polled individuals in the U.S. believed that ENDS were less harmful than cigarettes.\textsuperscript{19,20} However, in 2017 the majority of people polled in the U.S. believe that ENDS are as or more harmful than cigarettes.\textsuperscript{21,22} Shifts in opinion result from increases in evidence on the negative effects of ENDS, more familiarity with their risks, and prevention messaging.\textsuperscript{21,22}

According to the World Health Organization (WHO), ENDS emissions typically contain “nicotine and other toxic substances that are harmful to both users and those exposed to the vapors secondhand.”\textsuperscript{23} The WHO also notes that some products claiming to be nicotine-free have been found to contain nicotine. This messaging contributed to the shift in public opinion.

Further, risk factors of ENDS use reported by the WHO include the potential for “abusing or manipulating the product, use by children and adolescents who otherwise would not have used cigarettes, simultaneous use with other tobacco products (dual or poly use) and children and adolescents going on to use smoked products following experimentation with ENDS.”\textsuperscript{23}

Regulation of ENDS

Despite the serious costs of tobacco use in the United States, there is a lack of knowledge in how the use of ENDS has impacted State regulatory actions such as tobacco inspection and policy development.\textsuperscript{11} As ENDS are used more widely and research indicates their risks, regulative actions may become more common. Regulation including implementing restrictive State laws and policies of ENDS has been found to be particularly impactful among
youth and those who have never smoked cigarettes.\textsuperscript{11} Such policies reduce retail availability, ENDS access to youth via regulating prohibitions on access, and create limits on ENDS industry advertising.\textsuperscript{11}

There are many particular actions that may prevent ENDS use and underage purchase. Regulatory actions like prohibiting the sale of cigarettes and smokeless tobacco to "individuals under the age of 18, requiring retailers to verify a purchaser’s age by photographic identification, prohibiting free product samples and vending machines, except in adult-only facilities, limiting outdoor advertising, advertising in publications with significant youth readership, and advertising near schools and playgrounds, prohibiting the sale or distribution of brand-identified promotional nontobacco items such as hats and tee shirts, and requiring manufacturers to provide intended use information on all cigarette and smokeless tobacco product labels and in cigarette advertising\textsuperscript{11} have prevented the sale of ENDS to youth and prevented initiation of use.

These regulatory actions are increasingly important due to the risk factors of ENDS identified in recent studies.\textsuperscript{24} However, as noted further in this study only 23 States inspect for ENDS in their Synar inspections. This is a challenge that stakeholders must address while examining future policy interventions.

My study examined what is provided in the ASR concerning the presence of regulatory policies on ENDS in the inspection protocol- including where/how ENDS can be sold in a State. Regulatory policies listed in the ASR include: laws and regulations, law enforcement efforts,
activities that support law enforcement efforts, and anticipated changes in youth tobacco access legislation or regulation in the State.

As prevalence of ENDS use has become more common, studies on their use have evolved. In May of 2018, a study reviewed evolution of the e-cigarette market in Canada, a market that had high ENDS sales and usage. Policies around the time of this study permitted e-cigarettes to be sold legally and advertised with limited restrictions.

These policies allowed for study on the larger impact of increased ENDS availability to minors such as the impact of marketing such devices. In Canada, the percentage of youth surveyed who reported noticing e-cigarette promotions often or very often approximately doubled between 2017 and 2019. The study found that these respondents who reported noticing marketing often or very often were more likely to report vaping in the past 30 days, past week, and ≥20 days in the past month.25

These findings revealed that “exposure to marketing and the prevalence of vaping increased among Canadian youth after the liberalization of the e-cigarette market in 2018.”25 However, as Canada introduced regulations restricting e-cigarette marketing, an association was made with “lower levels of exposure to marketing and lower prevalence of e-cigarette use.”25

Youth access prevention has also been studied in the United States. In 2019 in Texas, two large cohort studies were aggregated to show that recall of retail store–based ENDS marketing at the start of the study period was associated with significantly higher odds of subsequent ENDS initiation among youth.26 This allowed the researchers to conclude that “marketing of ENDS at retail stores predicts youth and young adult ENDS initiation, and
marketing on TV predicts young adult initiation.\textsuperscript{26} Since youth are initiating and then using ENDS at a higher rate, they may be more likely to seek out these products at retail locations. Enforcement may be more effective when it targets products that are being marketed to and regularly obtained by the youth inspector demographic.

There have been a number of studies examining the relationship between tobacco retail density and ease of obtaining tobacco products. These studies indicate that limiting access to tobacco products is an essential aspect of youth prevention.\textsuperscript{27}

In a study that reviewed articles published until December of 2019, 40 articles were found related to this topic.\textsuperscript{27} The research was restricted to studies that “measured the density of and/or proximity to tobacco outlets and included associations with smoking outcomes.” The authors concluded that “higher density values were mostly associated with higher smoking prevalence (76.2%), greater tobacco use and smoking initiation (64.3%), and lower cessation outcomes (84.6%). Proximity measures were not associated with any smoking outcome except with cessation (62.5%).\textsuperscript{27}"

The Synar program and RVR itself have also been studied, with overall national weighted RVR average decreasing over time,\textsuperscript{8} with some year-to-year variation. In one study in 2018 researchers sought to determine if retailers that sell tobacco to adolescents are as “uncommon as government surveys find.”\textsuperscript{28} This study assumed that “Government-sanctioned surveys underestimate the extent of the problem, and retailer associations use these data to block stricter enforcement policies.”\textsuperscript{28} The researchers found a mean RVR across six rounds of checks to be 18.0%, with a range of 13.7% to 28.0% per round. This study was limited to suburban Denver, Colorado, only involved cigarettes, and did not reveal inspector age (although ensured
that they were under the age of sale). This may lead to an inaccurate depiction of RVR as it did not encompass the full range of tobacco products, inspector ages, or inspection regions. In the Synar program an inaccurate RVR could unfairly put a State at risk of penalty or result in providing incorrect information federally.

Recent study of the Synar program has determined that stores that sell tobacco to underage customers including youth inspectors are “more likely to be detected and penalized when youth inspectors carry identification during undercover tobacco sales compliance checks” as compared to not carrying identification with them. Furthermore, this study noted that “purchase attempts of vaping products (ENDS before deeming required consistent definition) were 35% less likely than cigarette purchase attempts to trigger an identification request and 42% more likely to result in a sales violation.” This reinforces the importance of including ENDS in inspections to obtain a true representation of RVR. The products that are requested should represent the breadth of products the inspectors are utilizing.

The Synar Program, Trends, and Youth Access

The Synar program itself has also been studied. An analysis of temporal trends among youth in Mississippi, the South, and the U.S. as a whole revealed that Mississippi and other study regions effectively restricted commercial access to tobacco via policy interventions such as age and product bans. This study concluded that Synar policy implementation has been “generally effective at deterring youth access to tobacco and, in many cases, has yielded declines in tobacco use.”
Another comprehensive descriptive study evaluated combined data on Synar violation rates from all States/years and assessed “the connection to national rates of cigarette sales and youth smoking behavior.” This study indicated laws prohibiting the sale of tobacco to juveniles appear to have had some degree of success, via slightly lower RVR in States with stronger prohibitions.

Joseph DiFranza has conducted significant research on the Synar program. In 2012, he developed a study noting that including enforcement in programs that “disrupt the sale of tobacco to minors will reduce adolescent smoking.” DiFranza found “little evidence that merely enacting a law without sufficient enforcement had any impact on youth tobacco use” and noted that “all enforcement programs that disrupted the sale of tobacco to minors reduced smoking among youth.”

These effective techniques noted by DiFranza included aggressive statewide efforts to limit tobacco sales via State and locality regulations and limiting youth from commercial access via State enforcement inspections with penalties.

In fact, DiFranza notes that adolescents who purchase tobacco are the primary sources for other youth. This was based on multiple studies conducted between 1997 and 2002 and therefore was not updated for the inclusion of ENDS. This would suggest, now that ENDS are the predominant tobacco product in this demographic, that youth may attempt to buy ENDS for other youth.

The disruption of commercial distribution creates supply shortages, driving up the cost of tobacco on the street and discouraging sharing among peers as smokers protect their supply.
In Texas it was demonstrated that enforcement resulted in a marked decline in smoking among middle school students and a simultaneous decrease in the number of commercial and social sources of tobacco.\textsuperscript{36}

Per DiFranza a comprehensive Synar program that has the greatest potential to significantly reduce tobacco sales to minors includes the following: Needs Assessment and Strategic Planning, Policy and Regulatory Approaches, Enforcement of Merchant Compliance, Interagency Collaboration and Networking, Community Education and Support, Including Media Advocacy, Merchant Education, Youth Involvement, Integration of Synar Into Overall Prevention Efforts, and Integration of Synar Into Statewide Tobacco Control Efforts.

DiFranza’s studies illustrate the importance of having effective enforcement strategies in place. SAMHSA has found that when efforts to control youth access have been multifaceted (as identified above) and involved various sectors of the community (tobacco retailers, enforcement agencies, and community groups), larger reductions in sales to minors have been achieved than when a single intervention has been tried (e.g., merchant education or legislation alone). Community groups can especially lead enforcement efforts via awareness programs and prevention education efforts. Closer collaboration between community groups, tobacco retailers, and government agencies make ENDS enforcement more effective.

Tobacco retailers have been extensively studied in the retail environment by examining licensing. Licensing has allowed the study of retailers by providing a near complete list of legal tobacco sales in a jurisdiction. Licensing allows a State to note number and location of retailers so they can effectively provide enforcement action. According to the CDC, there are at least
380,000 tobacco retailers in the United States, comprising of 5,000-10,000 that only sold e-cigarettes.\textsuperscript{35,36}

As of September 30, 2021, eight states, American Samoa, Guam, and Puerto Rico require retailers to have a license to sell cigarettes and other tobacco products over the counter. The definition of “other tobacco products” may or may not include ENDS. Thirty-two states, the District of Columbia, the Northern Mariana Islands, Palau, and the US Virgin Islands require retailers to have a license to sell either conventional tobacco products or e-cigarettes specifically over the counter.\textsuperscript{37}

Further, the average US store has nearly 30 tobacco marketing materials (eg, branded signs; branded shelving, such as power walls; branded functional items).\textsuperscript{38} In the USA, gas and convenience stores are the most common type of tobacco retailer and also have a higher prevalence of tobacco advertising than other retailer types.\textsuperscript{39} It is also noted that the majority of US adult smokers purchase their cigarettes at gas and convenience stores,\textsuperscript{40} and nearly half of youth visit convenience stores weekly.\textsuperscript{41} The variety and number of products available make it important to target products that are actually used by underage inspectors so an accurate RVR can be established.

**Retail Inspection**

It is important that a State has the best information available to make sure enforcement is effective, accurate, and represents the products being used by their regional demographic to ensure an accurate RVR.
Utilization of inspectors under 21 and use of ID has been studied in terms of retail inspections themselves. A 2021 study examined Tobacco 21 policy adoption and retail inspection in the United States from 2015-2019.\textsuperscript{42} The Study determined that the average retail violation rate of underage sales of tobacco products in T21 regions was lower than in non-T21 regions.\textsuperscript{42}

Additionally, a study was conducted on FDA’s retail underage inspection program where inspectors may not lie about their age or use fake identification which was suggested to reduce the program’s effectiveness.\textsuperscript{43} Another study compared youth flashing an ID quickly versus not using any ID. This study found that youth flashing of an ID resulted in 3.8 times greater likelihood of a sale compared to no flashing of an ID.\textsuperscript{44}

In one other study, “if asked for an ID (which happened 87\% of the time), the minor responded they had no ID or they provided an actual ID (which was marked "Under 21"). When the youth presented the ID, there was a significantly higher rate of sales, relative risk was 6.2 times greater, than when no ID was presented.\textsuperscript{45}"

Gaps in the Literature

The increase, impact, and risks of youth ENDS use (and dangers of the ease of retail availability), the importance and effectiveness of regulation, and large role enforcement plays in an effective tobacco prevention program have all been established through the studies summarized above. However, ENDS as a tobacco products inclusion impact on RVR in the Synar program has not been studied. This dissertation examined differences in RVR between States that include ENDS in their Synar inspections and those that do not in order to determine if their
inclusion negatively impacted RVR. Further questions of how other differences in what States include in their inspection protocol will also be addressed that may impact RVR.

Analyzing ENDS as a tobacco product in the Synar program and including other possibly associated measures of a comprehensive youth tobacco access program such as environmental factors around ENDS, youth inspector carrying ID, and age of youth inspectors allows for a more complete picture of youth tobacco access that has not yet emerged from previously available research.
References:


Chapter 3: Methods

Section 1: Specific Aims and Conceptual Framework

This study consisted of examining three Specific Aims to determine a series of independent variables’ impact, if any, on the dependent variable RVR (as shown in Figure 1). The variables examined in these three aims were: inclusion of ENDS in a States inspection protocol, States with high ENDS use and/or high retail availability as defined by YRBSS, and the Presence of State Regulatory Policies (including use of inspectors over 18 and carrying ID).

Specific Aim 1 sought to determine if States that inspect for ENDS sales have higher RVR, with the null hypothesis being that there is no impact of testing for ENDS sales on RVR. A State may be wary to include ENDS in their Synar sample if State stakeholders fear that including the devices will negatively impact its compliance standing.

Specific Aim 2 sought to determine whether States that have high ENDS use and retail availability as indicated by YRBSS will also have higher RVRs. The null hypothesis was that high ENDS use will have no association with RVR. The research question asked if States that have high ENDS use and retail availability as indicated by YRBSS also have higher RVRs as measured by their FY2020 ASR. States may think that a region that has ENDS highly in demand and highly available is more likely to be sold in Synar inspections, increasing RVR.

Specific Aim 3 sought to both review States that have regulatory policies on ENDS as well as determine if such as utilizing inspectors over the age of 18 and carrying ID had any association with RVR. The null hypothesis was that presence of such regulatory policies on ENDS noted in the ASR will not be associated with RVR. Regulatory policies on ENDS impact on
Synar inspections can be evaluated to determine their impact on RVR. While limited data was available in the FY2020 ASR, this can also serve as a starting point for future study.

**Conceptual Framework**

A PESTLE framework is utilized to highlight external factors that may contribute to States deciding upon including ENDS in inspections based on concerns that it would negatively impact their RVR. A PESTLE analysis is a commonly used strategic framework that examines (and serves as a mnemonic for) “political, economic, sociological, technological, legal, and environmental” factors. This conceptual framework as it relates to RVR is available in Figure 2.

No PESTLE analyses of tobacco retailing in the United States are currently available. However, a PESTLE analysis of the general retail environment in the East African Community was published in 2019. While this PESTLE analysis excluded tobacco retailers, it noted barriers to and opportunities for “effective and efficient commerce” that are generalizable and applicable to this analysis.

Barriers studied in the East African PESTLE analysis included “poor infrastructure, inadequate skills and training, and lack of legitimacy.” These challenges hampered the efforts of locally based retailers to expand reach in the region. Tobacco education infrastructure, retailer skills and trainings, and importance of limiting sales of ENDS to underage youth are factors that can be considered in the PESTLE analysis of sale of ENDS to youth.

Multiple studies using PESTLE analysis note political factors are a focus on a country's politics and identifying who had the power to influence major decisions. In the East African
study, political factors included political stability in countries where coups are not uncommon and how free individuals are in each country to live their lives without fear of government crackdowns. This ENDS analysis relates political factors as presence of ENDS in regulations and goals and priorities around tobacco of the political party in power in a State. My analysis includes ENDS presence State regulation as an independent variable as a political factor. Goals and priorities of a political power were not quantifiable in a manner that could be utilized in this study.

The East African study found economic factors may include both the retail consumption behavior of residents including disposable income of the study population as well as set governmental costs such as inflation and taxes. These findings can apply to disposable income of a State’s population to purchase ENDS and governmental costs involved with regulatory action and their impact on the consumer. Retail availability was studied to determine its impact on RVR due to accessibility of data in YRBSS. However, ENDS sales, cost of products, and retail consumption data (including regulatory costs passed onto the consumer) were out of scope of this study.

Sociocultural conditions, are noted in research as “crucial parameters in any analysis of a business environment because they constitute the context in which all interpersonal actions and business activities take place.” This allows “the broader societal and cultural context in which retailers operate is an important consideration”

Sociocultural factors involve the “peer pressure” and cultural norms around tobacco products in a State. Research has shown that adapting to the local culture can help
international retailers succeed in a foreign market. The East African study notes this as cultural diversity amongst the countries being evaluated. This focus on cultural diversity can be used by retailers and policy makers to adapt to State and customs around ENDS. This is especially applicable where States have differing relationships with ENDS use and the tobacco industry as a whole. Accessibility, cultural norms, and peer pressure were encompassed in my study as sociocultural factors. These factors were encompassed via examination of retail availability and high ENDS use relationships with RVR.

Technological factors include the continuous invention of new devices that regulators and elected officials are unaware of and therefore cannot request that they be addressed via legislation. Prior to the deeming rule, there were a wide variety of ENDS products available that regulators were not able to categorize and account for in policy. These were not regulated in terms of quality or market control. ENDS device availability and new device development are constantly evolving and were not able to be included in my analysis.

Legal factors such as citation and fine policy relate to the decision to include ENDS in already existing regulations. The local retail environment itself can include policies or practices that support or prevent ENDS sales in the State. ENDS being included in the Synar inspection protocol, policies requiring inspectors to carry identification, and use of inspectors under 21 are all “legal” factors included in this analysis. Presence of regulations and penalty structure were beyond the scope of this analysis due to the breadth of differences in each State.

Environmental factors can also relate to the impact of ENDS use in common spaces affecting others via secondhand smoke, air pollution, and discarded devices. Data availability to measure
impact on common spaces was confounded by multiple superfluous variables, while ENDS use in a State was used as an environmental factor in this study.

States and territories also may fear penalization for exceeding national RVR requirements. These factors may preclude States from determining the scope of illegal sales of ENDS to minors. This study seeks to understand the full association of ENDS on inspections. A summary of the PESTLE framework used in this study is available in Figure 3. Although there are wide ranging PESTLE contributors related to ENDS, a complete analytical examination of each contributor is beyond the resources and scope of this study.
References


Section 2: Methodology

Study Design

This was a cross-sectional study where Synar tobacco retail inspection data were examined from Federal Fiscal Year 2020 from 50 States and the District of Columbia which will be referred to as 51 States. A cross-sectional methodology was selected to answer the questions noted in specific aims. Specific Aim 1 addressed how many States that have high RVR inspect for ENDS in comparison with States with lower RVR. The presence of a relationship was examined to determine impact of including ENDS inspections on RVR.

In examining specific aim 2, YRBSS (retail availability of ENDS products and level of ENDS use in the State) and specific aim 3 other selected variables from the ASR (use of inspectors under 21 and carrying of identification) were also examined for association with high RVR. The objective of this comparison was to determine if independent variables identified in these aims were impacting RVR. Presence of regulations was not examined in statistical analysis due to small sample size and wide discrepancies in regulatory actions.

The cross-sectional design allowed estimation of the odds ratios to study the association between selected variables and RVR to determine any impact such variables have on heightened RVR. However, a cross-sectional design does not allow causal conclusions to be drawn. All RVRs were collected and listed from each of the 50 States and District of Columbia through manually reviewing each State’s 2020 ASR. High and low RVR breakdown is shown in Figure 4.
Data Sources

All Synar data being used is publicly available via State Behavioral Health websites based on SABG requirements. Detailed ASR information (including information on youth inspectors, adult inspectors, and individuals cited) is collected without being identifiable; for instance, age and gender of a youth inspector may be used to compile statistical frequencies, but no name, address, or identifiable detail is added. Data collection is identified in Figure 5.

Comparison data relating to independent variables (i.e. presence of ENDS in the inspection protocol, and presence of regulatory policies such as use of inspectors under 21, and carrying ID) was sourced from public YRBSS databases. Data from the ASR and YRBSS was linked by State. YRBSS did not have data for all States, creating some missing values.

This study also utilized publicly available Centers for Disease Control and Prevention (CDC) Youth Risk Behavior Survey System (YRBSS) data to determine linkages to Synar underage smoking program data regarding association of Electronic Nicotine Delivery Systems (ENDS) usage. All other data elements were gathered from individual State ASRs.

Data Collection and Cleaning

Annual Synar Reports were compiled from individual State Behavioral Health Websites. These sites either have an ASR publicly posted or information on how to find or request it. Reports were collected for all 50 States and the District of Columbia. Information related to RVR, age of inspector, use of identification, and policy information were directly available in the ASR.
A list of all RVRs and data for independent variables were transcribed from the ASR and created as a list in Microsoft Excel. Data was collected for State RVR, Retail Availability of ENDS, ENDS Use in State, Use of Under 21-Year-Old Inspectors, ENDS Included in Inspections, Inspectors Carry ID, Any Change in Law Regarding Inspections, and Other Changes in State Law. These variables are indicated by yes or no checkboxes on the ASR.

This data was sorted by State and variable and imported into Stata/BE 17.0 for Windows (64-bit) and SAS V. 9.4. RVRs were dichotomized into categories of high RVR and low RVR with RVRs over 10% considered high based on SAMHSA guidance and RVRs under 10% low risk for lack of compliance with Synar requirements.

Guidance surrounding 10% being used as a cut off for high and low RVR can be found in every published SAMHSA Annual Synar Report spanning 2010 to 2015 (the last year a Synar report was published). Each report notes the number of States above and below the 10% threshold. The 2015 Report notes that “research suggests that for youth tobacco access efforts to demonstrate a reduction in youth tobacco use, the retailer violation rate must be below 10 percent.”

Data Analysis

To obtain statistical significance of the relationship, metrics involving correlation were examined via STATA to determine the strength of any association. A coding system was devised where high RVR would be noted as “1” and low RVR noted as “0.” Presence of ENDS in youth inspections was noted with a “1” and lack of ENDS inspections were noted with a “0.”
The inspection data from FY 2020 was analyzed for their overall RVR and association with ENDS. The States that inspect for ENDS and utilization of inspectors under 21, inspectors carrying ID during an inspection as reported in a State’s ASR were utilized for comparison analysis to assess each variables association with RVR. All specific aims and the variables used to address them can be found in Table 1.

The chi-squared statistic was utilized to determine differences amongst the categorical variables such as presence of ENDS and high RVR. The chi square statistic indicated how much difference exists between observed counts and what would be expected if there was no relationship. Fisher’s exact test was reported due to the small size of the counts in this study, with sample sizes in some cells five or under. Fisher’s exact tests were exclusively utilized when sample sizes were too small to report chi-square and odds ratios.

Data were input into STATA BE 17 via coding. A coding system was devised for the independent variables where each independent variable (i.e., presence of ENDS in the inspection protocol, use of inspectors under 21, carrying ID) were indicated. This was set up as a simple yes/no where presence of the independent variable was indicated as a one and absence was noted as a zero. High RVR was noted as a one and low RVR was noted as a zero.

Tests of correlation were used between inspection for ENDS and State RVR and odds ratios were determined. The study hypothesizes that States that inspect for ENDS will have no impact on RVR. State officials may fear that inspecting for ENDS will lead to a higher RVR and avoid inspecting for ENDS as a result. States officials are likely aware that youth rates of ENDS use are high and assume that a typical youth inspector may be more likely to be sold an ENDS
product than a traditional tobacco product. Additionally, States that have high ENDS use and retail availability as indicated by YRBSS measure of currently used electronic vapor products frequently will also have higher RVRs. Correlation tests were conducted in SAS 9.4.

The overarching goal of this study was to determine whether including ENDS in youth inspections has any impact on the Retail Violation Rate, and if any measurable environmental factors in the State have an impact on the outcome.

**Methodology for Analyzing Data for Specific Aim 1:**

The ASR was reviewed to determine which States inspected for ENDS. For this aim, the independent variable was presence of ENDS in a State’s inspection protocol in Appendix C of its ASR. Under inspection protocol, a State must list the type of tobacco products that are requested, with ENDS as one of the options. There is an additional category of “other” as well. They also must describe the protocol for identifying what types of products and what brands of products are requested during an inspection.

State definitions of ENDS devices may differ, so the FDA definition of ENDS of “Vapes, vaporizers, vape pens, hookah pens, electronic cigarettes (e-cigarettes or e-cigs), and e-pipe” was used. If a State protocol mentions one of these terms in its “other” category of the ASR, an ENDS device will be considered present.

A direct relationship between States that inspect for ENDS and RVR was established. To do this, RVR for each State for FY2020 was compiled from its ASR by reviewing each ASR from all 50 States and District of Columbia manually. A State reports its RVR as a part of its annual submission. The RVR is noted as a numerical percentage in each State submission of their ASR.
and corresponding excel spreadsheets with quantitative information. Figure 4 lists each State and indicates whether the State assesses ENDS sales along with their RVR.

**Methodology for Analyzing Data for Specific Aim 2:**

The second aim of this study sought to determine if states that have high ENDS use and retail availability as indicated by YRBSS will also have higher RVRs. For this objective, the first independent variable is high ENDS use in a State as indicated by 2019 YRBSS measures of ENDS use by State. The null hypothesis was that high ENDS use will have no association with RVR. RVR was identified and sorted in the same manner as noted in Aim 1.

This was set up as a simple dichotomized yes/no where high ENDS use is present or is not. States that have an environment of high ENDS use and retail availability to youth may be more accustomed to selling such products to youth, and be more likely to have a sales violation and higher RVR.

Analysis also involves frequencies (and percentages) to examine the distribution of the RVRs for States that inspect for ENDS. A similar table to Aim 1 illustrated if States that have high ENDS use are more likely to have higher RVRs. However, to obtain statistical significance of the relationship more extensive testing occurred.

If the percentage of youth currently used electronic vapor products frequently (including e-cigarettes, vapes, vape pens, e-cigars, e-hookahs, hookah pens, and mods, on 20 or more days during the 30 days before the survey) is over the national average of 10.7%, the State will be marked as having high ends use. This high ENDS use measure was compared to
States with RVR for analysis to help determine a relationship between high environmental ENDS use and RVR.

The second independent variable measured was high percentage of youth who were able to obtain ENDS in a retail environment. This was determined by 2019 YRBSS data of store-bought vapor products by youth. This is defined as youth responding to the YRBSS who “Got Their Own Electronic Vapor Products By Buying Them In A Store (such as a convenience store, supermarket, discount store, gas station, or vape store, including e-cigarettes, vapes, vape pens, e-cigs, e-hookahs, hookah pens, and mods, during the 30 days before the survey, among the % of students nationwide who currently used electronic vapor products and who were aged <18 years).” This field was deemed high if it was over the national average of 8.1%.

Figure 7 indicates RVR and retail availability as indicated by YRBSS.

The YRBSS data from 2019 was the latest data available and compares well with Synar data used from FY 2020. Utilizing national averages to obtain high and low values is based on standard practice.

However, frequencies (and percentages) were calculated to look at the distribution of the RVRs in States that have regulatory policies on ENDS. A similar graphic to Aims 1 and 2 illustrates if States that have regulatory policies on ENDS are more likely to have lower RVRs.

The ASR responses were reviewed for State reporting of a change that may impact ENDS protocols. The responses to these ASR questions were examined for indication of change by reviewing the changes in policy checkbox and tabulated.
Methodology for Analyzing Data for Specific Aim 3:

The third aspect of the study sought to determine if States that have regulatory policies on ENDS have higher RVR. The dependent variable for Aim 3 was RVR. The RVR was identified and sorted in the same manner as noted in Specific Aims 1 and 2. For this aim, the independent variable was if States have a legal framework including any regulatory policies on ENDS. A law or regulatory policy can be noted via information provided in the ASR (available in appendix A). The ASR asks if a State has any changes in State law that impact the State’s protocol for conducting Synar inspections including if it:

- Changed to require that law enforcement conduct inspections of tobacco outlets
- Changed to make it illegal for youth to possess, purchase or receive tobacco
- Changed to require ID to purchase tobacco
- Changed definition of tobacco products
- Other change(s) (Please describe.)

The ASR also asks if there have there been any changes in State law that impact the following:

- Licensing of tobacco vendors
- Penalties for sales to minors
- Vending machines
- Added product categories to youth access law

The list of data gathered for this aim included States that have regulatory policies on ENDS and those that do not, as defined by what is listed in the ASR. This data was gathered for interest on depicting the complete picture of tobacco access in a State, however individual policies and laws were not evaluated for positive or negative impact on youth tobacco use and therefore were not analyzed utilizing association analysis.
References (analytical tools)


Use of Stata/BE 17.0 for Windows (64-bit)
Use of Excel (Microsoft Office V. 18)
Use of SAS V. 9.4

Protection of Human Subjects

IRB approval determination from the Johns Hopkins Bloomberg School of Public Health

IRB was obtained before initiating any data analysis noted in this dissertation. This research was not deemed as involving human subjects.
Chapter 4: Results

Section 1: Specific Aim 1, Determining whether ENDS Inclusion in State Synar Inspection Impacts RVR

Of the 50 States and District of Columbia, a total of 17 States (33%) had high RVR and 34 (57%) States had low RVR. Figure 6 depicts RVR and inclusion of ENDS in FY2020 Synar inspections. 23 States out of the 51 (45%) evaluated inspected for ENDS sales; Comparison analysis was used to show that seven (14%) of the 51 States had high RVR and also had youth inspectors inspect for ENDS. Nineteen States (65%) had low RVR and eight States (35%) had high RVR. Additionally, there were ten States (20%) that had high RVR that did not inspect for ENDS and 18 States (35%) that had low RVR and did not inspect for ENDS.

States that do and do not inspect for ENDS were further classified by high and low RVR (Table 2). For the 28 States that did not inspect for ENDS, 19 (68%) had low RVR, while nine (32%) had high RVR. When the 23 States that inspected for ENDS were examined, 16 (70%) had low RVR and seven (30%) had high RVR.

While dichotomization of ENDS to high/low may impede precise measurements, it allowed States to be grouped with like States for analysis, and ultimately share best practices in ensuring low RVR with those that are in similar situations. Individual analysis of each of the 50 States and District of Columbia RVR may not allow States to work with others to respond to ENDS.
Seven States (14%) that inspected for ENDS had high RVR, while 16 States (31%) that inspected for ENDS did not have high RVR. Eight States (16%) had high RVR and did not inspect for ENDS, and 20 States (39%) did not have RVR or inspect for ENDS.

The result was to fail to reject the null hypothesis of no association between inspection for ENDS and high RVR (p-value of 0.6909, Chi-Square .1581. (The odds ratio is .79 (95% CI 1.2 43-2.556).
Section 2: Specific Aim 2, Determining if states that have high ENDS use and retail availability as indicated by YRBSS also have higher RVRs

States that do and do not have high youth environmental ENDS use as reported by YRBSS were classified by high and low RVR (Table 3). For the 19 States that did not have high environmental ENDS use, 11 (58%) had low RVR, while eight (42%) had high RVR. When the 25 States that had high environmental ENDS use were examined, 18 (72%) had low RVR and seven (28%) had high RVR.

Fisher’s exact test scores were examined for high environmental ENDS use in the State resulting in a failure to reject the null hypothesis of no association between high ENDS use and high RVR (p-value of 0.9573, chi square .0029, OR .96, 95 CI .203-4.524).

When all 50 States and the District of Columbia were examined with frequency analysis nine States had high ENDS use, with 35 States (18%) having ENDS use under the national average. Seven States (14%) not reporting any data for this measure and were excluded from analysis. Seven States (14%) with high RVR had high ENDS use while eight States (16%) with high RVR had low ENDS use. 18 States had low RVR and high ENDS use and 11 States (22%) had low RVR and low ENDS use. Figure 7 indicates RVR and high ENDS use measured by YRBSS by State.

Additionally, States that do and do not have high ENDS Retail availability as reported by YRBSS were further classified by high and low RVR (Table 4). For the 21 States that did not have high ENDS Retail availability, 16 (76%) had low RVR, while five (24%) had high RVR. When the
15 States that had high ENDS Retail availability use were examined, eight (53%) had low RVR and seven (47%) had high RVR (Fisher’s p-value of 0.0022).

The resulting p-value from high retail sales in the State and high ENDS use was .0022 using Fisher’s exact, allowing rejection of the null hypothesis of no association between purchase rate of vapor products in a retail store and high RVR.

Analysis of storebought vapor products by youth using the population of 50 States and the District of Columbia revealed that 24 States (47%) had higher purchase percentage than the national average, while 12 States (24%) had a purchase percentage below average, and 15 States (29%) did not have any reported data.

Eight states (16%) had high purchase percentage and high RVR and eight states (16%) had low purchase percentage and low RVR. Sixteen states had low purchase percentage and high RVR, and 12 States (24%) had low purchase percentage and low RVR.
Section 3: Determining whether States that have regulatory policies on ENDS, utilize inspectors over age 18, or have inspectors carrying ID has an association with RVR.

In the FY2020 ASR all 51 States were examined for self-reported changes in State law. There were four States (8%) that noted changes in State law that impact the State’s protocol for conducting Synar inspections. Seven States (14%) had a change in State law that impacted licensing of tobacco vendors, increase of penalties for sales to minors, vending machines, and added product categories to youth access law. Two States (4%) had both changes in State law that impact the States protocol for conducting Synar inspections and other changes in the State law. This resulted in nine States (18%) with any changes overall in State law. Changes in law are indicated in Figure 8.

Changes in laws that impact Synar inspections and RVR were examined in frequency analysis for FY2020, where the denominator of States included the total number of States examined, or 51. Two States (4%) had high RVR and changes in laws that impact inspections and 15 States (29%) had high RVR and no changes in laws that impact inspections. Two States (4%) had low RVR and changes in laws that impact inspections, while 32 (63%) States had low RVR and no changes in State law that impacted inspections. Changes in law and RVR is noted in Figure 9.

If a State has regulatory policies in place penalizing sale of products to youth, retailers may be more likely to share knowledge and rules or penalties noted with such polices with their clerks, allowing more awareness for refusing sales. Changes in policies may have different impact across States, as some States may not be as knowledgeable or communicative with
retailers as others, which lead to gaps that make comparing policies challenging. In fact, some changes in laws or policies noted by a State make tobacco access easier for youth.

As noted, the ASR also collects other policy and State regulation information in their Appendix C inspection protocol. Of this information, State use of inspectors under age 21 and carrying identification (ID) were selected to examine for any relationship with RVR.

Data frequencies utilizing the total number of 51 States showed that in FY2020 12 States (24%) used youth inspectors under 21 years old and 39 States (76%) used inspectors under age 18. As related to RVR, five States (10%) used inspectors under 21 and had high RVR and seven States (51%) used inspectors under 21 and had low RVR. Twelve States (24%) used inspectors under 18 and had high RVR and 27 States (53%) used inspectors under 18 and had low RVR. Figure 10 indicates RVR and use of over 18-year-old inspectors.

States that do and do not have use inspectors over 18 years old were further classified by high and low RVR (Table 5). For the 37 States that did not have inspectors over 18, 26 (70%) had low RVR, while 11 (30%) had high RVR. When the 14 States that did use inspectors over 18 years old were examined, nine (64%) had low RVR and five (36%) had high RVR.

The resulting descriptive statistics for use of inspectors over 18 years old and RVR indicated a p-value of 0.4857, Chi-Square 0.486. The odds ratio is 1.61 (95% C.I. 1.124-6.101).

The total number of States (51) was also used to calculate that 22 States (43%) had youth inspectors that carried ID and 29 States (57%) did not. As related to RVR, 12 States (24%) had high RVR where inspectors carried ID, and 10 States (20%) had low RVR where inspectors
carried ID. Six States (12%) had high RVR where inspectors did not carry ID and 23 States (45%) had low RVR where inspectors did not carry identification. Figure 11 indicates RVR and use of inspectors that carry ID.

States that do and do not have inspectors carry identification were further classified by high and low RVR (Table 6). For the 28 States that did not have inspectors carry ID, 23 (82%) had low RVR, while five (18%) had high RVR. When the 23 States that did have inspectors who carry ID were examined, 12 (52%) had low RVR and eleven (48%) had high RVR.

The resulting descriptive statistics for carrying identification and RVR indicated (p-value of 0.0318, Chi-Square 4.606. The odds ratio is 3.83 (95% C.I. 1.243-13.076). P-values, 95% confidence intervals, chi-square statistics, odds ratios, and P-values for Fisher’s exact test in Table 7. Table 8 reveals RVR and complete findings for selected variables by State for the FY2020 Synar inspections.
Chapter 5: Summary and Discussion

Section 1: Conclusion

The results illustrated (Table 2, Table 3) that inclusion of ENDS in a State’s inspection protocol does not influence RVR to a strong enough degree that will impact compliance. Inclusion of ENDS and other variables analyzed in a Synar inspection allow a State to see a full picture of tobacco use. Results are related to Specific Aims in Figure 12.

ENDS use has negative implications on youth, as described in background research and in greater detail below. It is therefore important for states to understand the scope of youth using ENDS and inspecting for ENDS is one of the effective tools for gaining this understanding. Despite its importance, however, a State may be fearful that including ENDS in its Synar sample may increase its RVR and subject it to penalties regarding its SABG. This study should alleviate such concerns and encourage states to pursue accurate reporting for youth ENDS inspections.

The data from this study begins to determine the impact of inspecting for ENDS sales on RVR of States. The data suggests that Federal partners and States should encourage inspections that include ENDS and other variables that allow for an accurate depiction of all tobacco products in the State.

Including ENDS in a State’s Synar inspections in FY2020 had no significant association with increased RVR, and therefore does not impact compliance. Youth access to ENDS in retail locations had stronger impact on increasing RVR, and therefore ENDS should, in fact, be
included in Synar inspections so a State can have a more accurate idea of youth access in order to target prevention resources and strategies.

Results indicated that retail availability of ENDS in a State and requiring youth inspectors to carry identification were associated with high RVR. Inclusion of ENDS in an inspection, high ENDS use in a state, and presence of regulatory policies on ENDS were not associated with high RVR.

Per Dr. Arnold Levinson, youth inspectors carrying ID resulted in higher sales violations. Dr. Levinson’s study involved asking for identification and retail tobacco sales to minors. Data from an unidentified Federal program from 2017-2018 was utilized to examine underage inspections. Results showed that violations after identification requests constituted 22.8% of all violations and were “nearly 3 times as likely when minors were required to carry identification in compliance checks.”

There are several reasons for this. One may be that States maintain vertical identification cards for youth under age 21 and horizontal identification cards for ages greater or equal to 21. This enables retailer to visually determine if a customer is old enough to purchase alcohol. However, study reveals that vertical identifications have not prevented underage tobacco sales, possibly “because the vertical orientation signified the bearer was younger than 21 although the sales age for tobacco was 18.” Furthermore, there is the possibility that the retailer does not check the identification, just notes its presence as permission to make the sale.
Additionally, violations were 42% more likely when minors asked for a vaping product versus cigarettes.\(^{46}\)

Tobacco retail policy has also been studied extensively. A study on tobacco retail licensing and product use conducted in California in 2019 examined 14 political jurisdictions with varying tobacco retail licensing ordinances. These ordinances were graded from strongest to weakest. The study found that the risks of initiation and initiation with past 30-day use were lower in jurisdictions with stronger tobacco retail ordinances.\(^{47}\)

This Californian study also had stronger associations present among participants who were still living in their same location in a follow-up evaluation, which indicated that the benefits of good tobacco retail licensing policy extended both “beyond cigarette use to e-cigarette use and into early adult life at age 18 when the sale of tobacco products was legal at the time of the study.”\(^{47}\)

The study in California helped show that robust regulation of tobacco products can mitigate the impact of long term routine availability of such products, potentially limiting sales, and therefore RVR. Additional examinations of tobacco regulation and interventions have noted their effectiveness in relation to the sale of tobacco to minors.\(^{47}\)

Such studies noted that key regulatory features that are reported to reduce both sales to minors violations and youth cigarette use include a mandatory tobacco retailer licensing fee to provide sustainable funding of undercover decoys to make at least one annual visit to each vendor and fines or penalties for violations.\(^{48,49}\)
There was little evidence that enacting a law without enforcement had any impact on youth tobacco use, while merchant education programs and enforcement efforts that did not reduce the sale to minors had no impact on youth tobacco use. All enforcement programs that disrupted the sale of tobacco products to minors reduced smoking among youth.\textsuperscript{49}

Section 2: Discussion

The results of these studies combined with previous research\textsuperscript{42} mentioned can inform policy for youth ENDS retail inspections. The results may help limit ENDS sales to minors while also ensuring that States comply with federal target rates. A State should not fear negative impact on RVR by including ENDS in its Synar inspections; reporting ENDS results can help illuminate youth ENDS use in each State, and will be unlikely to result in data that will penalize the State for noncompliance. Youth ENDS use data on RVR can be utilized by policy makers to develop interventions for curbing youth ENDS use.

Strengths

This is the first study to examine the association between a State’s youth tobacco inspection compliance and the prevalence of ENDS use in each State, whether the State’s inspection protocol includes ENDS, and some aspects of the State’s regulatory policy on ENDS. This study provided essential information needed for States to make programmatic decisions on what tobacco products inspect for to ensure their Synar program has a comprehensive representation of products youth are using. States can make program policies based on these
study outcomes regarding the inclusion of ENDS and be informed of their potential impact on federal regulatory requirements.

As previously noted, a State would not need to fear the negative impacts of a higher RVR by simply including ENDS in their youth inspections. Additionally, there is limited impact of other factors such as inspector age and regulatory environment of the tobacco programs. Given this limited impact, the State would also be able to examine and implement policies and regulations around Synar inspections freely based on State concern.

**Limitations**

The limitations of this study include the time period analyzed. Federal Year 2020 is the last year to have a State subjected to the 40% SABG penalty for lack of compliance. A State’s stakeholders may be less concerned about lack of compliance with the prospect of a 10% penalty rather than a 40% penalty of its SABG.

Decreasing the SABG penalty to 10% may allow a State to have more aggressive changes in their inspection protocol that would not be detected at the time of the study. These changes may include adding additional products and categories to their inspection protocol that were not present in FY2020.

Additionally, the ASR data reported does not allow this study to consider substate (i.e., city or county level) restrictions on sales that may differ from State-wide efforts. This may skew RVR in certain States where a high concentration of inspected outlets may be selected that
have sale restrictions that are stricter than State law. Substate preemption is an important factor in tobacco control.

Only information provided in the ASR was utilized, so if a State has regulations not noted, they were missed. However, the ASR has a wide variety of regulatory policies listed, and is an official Federal Government document, so is held to the highest standards of accuracy.

Other studies have noted that the tobacco industry utilizes strategies “to secure state preemption, public health community responses to preemption, and the impact and effects of state preemption of local tobacco control." Preemption plays a role in Synar inspections, as retail locations randomly sampled in a State may fall into locations with varying tobacco product and age guidelines. This may make a retailer more or less likely to sell to minors based on their local laws and policies and limit generalizability within and between States.

One such study in 2020 reviewed “peer-reviewed literature, reports, and government documents pertaining to tobacco control preemption” in order to create a public health framework. This framework determined that State preemption “has been detrimental to tobacco control by dividing the health community, weakening local authority, chilling public education and debate, and slowing local policy diffusion." Some stakeholders believe that Federal preemption is necessary to ensure they can inspect for ENDS, while others believe that their State or locality knows their populace best.

Examining State level data may contribute to an incomplete picture of RVR in a State by not considering local areas with stronger laws or areas where tobacco control advocacy is strong but State preemption impedes stricter policies. This may lead to lower RVR than the
State actual RVR if random sampling selects more retail locations in this area or higher RVR if less locations are selected.

Another limitation is the variation between ENDS costs and combustible cigarette costs. ENDS may cost more than combustible cigarettes, preventing some States from allocating funds to include such products in their sample due to the State funds allotted for consummated buys of tobacco products. Budgets may not allow for a full scope of ENDS to be included in inspection protocols.

Price differential between ENDS and combustible tobacco was studied in a 2017 sample of 45 countries. A comparison was made among the price of combustible cigarettes, disposable e-cigarettes and rechargeable cigarettes. It was determined that comparable units of combustible cigarettes cost less than disposable e-cigarettes in almost every country in the sample. The study accounted for the e-liquids found in rechargeable e-cigarettes that may cost less per comparable unit than combustible cigarettes by noting that the initial startup cost to purchase a rechargeable e-cigarette presents a significant cost barrier to switching from smoking to vaping.

This is relevant in determining what products a State may request in a youth inspection based on the fact that Synar is an unfunded mandate. States must allocate their own resources to enforcement. Furthermore, these products may also be sold online, where States may not have jurisdiction or ability to track down youth procurement of ENDS. Online sales may increase the number of youth ENDS users in the environment, and not allow for a full depiction of measures of high ENDS use in the locality.
Furthermore, in FY2021 Tobacco 21 legislation passage allowed all States to increase the age of youth inspectors and requires them to make this increase in their Synar inspections by FY2024. In this study, use of under 21 year old inspectors did not have an impact on high RVR, although 12 States used inspectors under 21.

The overall impact of utilizing older youth inspectors in all States is beyond the scope of this study. Only 12 States (24%) were utilizing such older inspectors at the time of the study. A complete data set of utilizing under 21 inspectors for all 51 States may associate with high RVR positively or negatively. However, using older inspectors in this data set did not result in increased RVR.

This study did not address online sales for ENDS. While this is an emerging avenue for youth to obtain these products, it was beyond the scope of this study. There is no method for the ASR in its current form to account for these purchases in order for data to be collected to analyze.

Social issues were also not analyzed. There was no way to quantify how issues like peer pressure and cultural norms impacted the results of the study.

The tobacco industry also has its own mechanisms for minimizing sales to youth. These strategies may influence Synar program enforcement, but the linkage is unclear. These issues are examples of opportunity for future ENDS study.
Potential Practice and Policy Implications

The practice and policy implications of this study are extremely relevant to State Synar programs and the data presented here can be a powerful aid to States when considering what products to include in their inspection protocol. States are faced with the concern of trying to depict an accurate sample of underage sales of tobacco products in their State while remaining in compliance with Federal requirements.

In addition to possible negative health impacts previously discussed, two studies have shown that there are increased odds of adverse school outcomes among youth with e-cigarette usage. E-cigarettes have been associated with lower grades in school in a large 2017 cross-sectional study of US high-school students. Similar results were found in a 2021 follow-up where youth ENDS users had higher odds of reporting grades that were mostly C’s or lower than youth with no use.

While the benefits of including ENDS in a Synar inspection are high, there are risks in including ENDS in inspections as well. Risks include concern the time and resource effort allocated to providing youth inspectors education on additional tobacco items to select from a retailer. Additionally, the financial cost for an ENDS product may be higher. Education on what devices to select can be completed and buys could become unconsummated, where a youth would not be required to take the product with them or refund the purchase.

Many organizations have stressed the importance of regulating ENDS on a federal level. In 2019 the American Academy of Pediatrics (AAP) called for immediate federal intervention to restrict the marketing and sale of e-cigarettes to young people in its policy statement “E-
cigarettes and similar devices. The AAP notes that discrepancy in youth obtaining and using ENDS devices may be due to “significant gaps in e-cigarette regulation.” The AAP further stated that federal laws and regulations do not appropriately restrict the advertising of e-cigarettes to youth.

There is a clear danger of advertising related to ENDS use. A longitudinal study from 2018 to 2020 showed that young adults show an increasing rate of e-cigarette use with an increasing rate of advertising exposure.

Additionally, individuals over 18 years old were also found to be susceptible to advertising. In fact, a study using data from the 2013–14 National Adult Tobacco Survey found that exposure to e-cigarette advertising appeared to be positively associated with the use of e-cigarettes and cigarettes among adults of all ages.

Further, the AAP notes that “the delayed implementation of the FDA Deeming Rule allows all e-cigarettes currently on the market to continue to be marketed and sold to consumers without FDA review through 2022” allowing youth access. To address this, the AAP calls for a critical need for “e-cigarette regulation, legislative action, and counter promotion to help youth live tobacco-free lives.”

Tobacco Policy Environment Characteristics

A study on local retail tobacco environment regulation published in 2019 has reviewed sociodemographic and policy environment characteristics of early adopters of retail tobacco control policies in differing US localities. Retail tobacco control environment policies were
examined via retail marketing surveillance, noted as performed by states and localities on an ongoing basis or as part of specific tobacco control awareness or policy campaigns.\textsuperscript{58}

Results of their review indicated that “localities with lower smoking rates or higher excise taxes were more likely to have adopted a retail policy by late 2015.\textsuperscript{57}” In addition, these “early adopters” were less likely to have voted majority Republican in the 2012 election or to have higher percentages of African American population.\textsuperscript{57}

The same study further noted that in the absence of federal and state restrictions on the retail environment, “local jurisdictions are increasingly adopting retail tobacco control policies to counter the tobacco industry’s pervasive influence at the point of sale.\textsuperscript{57}” The authors noted that in their sample of 80 US counties, half of them had adopted at least one retail tobacco control policy by late 2015. The adopters were diverse in income and race, as well as in tobacco control program capacity, preemption environment, and political party alignment.\textsuperscript{57}

The study on local retail tobacco environment concluded that the “probability of adopting a retail tobacco policy was much greater in counties with lower smoking rates and higher excise taxes, suggesting that localities where tobacco control efforts have been successful may have an advantage in pursuing retail tobacco policies. Conversely, localities with higher smoking rates, lower excise taxes, and higher proportions of priority populations were less likely to have adopted a retail policy; however, these communities stand to benefit more from policies aimed at reducing the omnipresence of tobacco products, because traditional tobacco control efforts have been less successful.\textsuperscript{57} The regulatory action seemed to have worked best with an already receptive audience, indicating that slowly introducing retail
policies may be most effective. However, popular support for such policies does seem to increase over time once retail policies are implemented.57

Previous research combined with this study leaves a clear indication that States should attempt to inspect for a complete range of tobacco products including ENDS in order to get an accurate depiction of youth tobacco access. The 2019 study on local retail tobacco environment research summarized that “localities with greater access to resources, eg, human and financial ones, along with more political will or policy options, are also more successful in efforts or at least more likely to adopt retail tobacco policies. State preemption takes away potential resources and options for local tobacco control programs.57”

Proven methods for enforcement include knowing where tobacco retailers are located, performing routine store surveillance to know which types of products, promotions, and marketing are most prevalent in each neighborhood, and paying for and facilitating enforcement of other local retail policies noted as effective by community stakeholders for what works best in their communities.

A State must consider developing effective tobacco licensing. Effective tobacco licensing allows a State to get a complete true depiction of the number of retailers in the State so they can utilize inspections for a range of products within the illegal age range, and ensure effective policies like strong fines to retailers to best provide these enforcement methods. Effective tobacco licensing helps ensure that resources are not misused on retailers that are out of business or no longer selling tobacco products. Funding to educate youth inspectors on what
products to buy as well as general state retail education on preventing sales to youth may help address such considerations.

The results from this study will allow stakeholders such as State policymakers to help limit ENDS sales to minors. Stakeholders can limit sales utilizing this data to help inform a comprehensive tobacco program that includes ENDS. As previously noted, a comprehensive tobacco program has a strong and complete enforcement component that targets a wide range of products that youth use.

The results also show that including ENDS and other variables that may be feared damaging to Synar compliance do not have a strong negative impact on RVR. Therefore, a State can include ENDS while also ensuring they are in compliance with federal target rates. The State can then effectively target funding and other resources to best maximize effective tobacco youth inspection tools. These results can be distributed widely to diverse stakeholders including State tobacco prevention specialists, industry representatives, and federal government tobacco specialists to ensure proper and pervasive action. Knowledge of the impact may lead to adjustments in promotion and availability of ENDS.
References


49. DiFranza JR. Which interventions against the sale of tobacco to minors can be expected to reduce smoking? *Tob Control*. 2012;21(4):436–442


<table>
<thead>
<tr>
<th>Aim</th>
<th>Dependent Variable</th>
<th>Dependent Variable Measurement Method</th>
<th>Independent Variable(s)</th>
<th>Independent Variable Measurement Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>RVR (obtained from State ASR)</td>
<td>Noted as percentage in State ASR and categorized as high/low (&gt;10%/&lt;10%)</td>
<td>Presence of ENDS in inspection protocol including (vapes, vaporizers, vape pens, hookah pens, and electronic cigarettes (e-cigarettes or e-cigs). Defined as (Yes/No)</td>
<td>ENDS product is listed for in inspection protocol by State/territory</td>
</tr>
<tr>
<td>2</td>
<td>RVR</td>
<td>Noted as percentage in State ASR and categorized high/low (&gt;10%/&lt;10%)</td>
<td>States that have high ENDS use and High retail availability as indicated by YRBSS</td>
<td>Determined cut off by national average level by YRBSS reports (10.7% for high ENDS use and 8.1% for retail availability)</td>
</tr>
<tr>
<td>3</td>
<td>RVR</td>
<td>Noted as percentage in State ASR and categorized high/low (&gt;10%/&lt;10%)</td>
<td>Presence of changes in Regulatory Policies on ENDS including inspection and other state law as well as current regulations on carrying ID and utilizing inspectors over age 18.</td>
<td>Listed in State ASR</td>
</tr>
</tbody>
</table>
All data is obtained from the BGAS reporting system, where all States submit annual reports. Quantitative information such as RVR are manually pulled from Excel spreadsheets that States are required by regulation to list their descriptive statistics on. Inspection protocol information was pulled from required qualitative attachments that provide this information and categorized per listed methodology and are available in the appendixes. All of these data are publicly available via a citizen access account to BGAS or direct correspondence with a State.

**Dependent variables:** The dependent variable is RVR.

**Independent variables:** Inclusion of ENDS in youth inspections, High ENDS use in a State, Retail availability of ENDS in a State, Inspector Carrying ID, Use of Inspectors over age 18.
**Table 2.** Comparison of Retail Violation Rates (RVRs) for States that Do and Do Not Inspect for ENDS*

<table>
<thead>
<tr>
<th>Retail Violation Rate (RVR)</th>
<th>Inspect for ENDS</th>
<th>Total Number of States</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Number</td>
<td>Percent</td>
</tr>
<tr>
<td>Low (&lt;10%)</td>
<td>19</td>
<td>68%</td>
</tr>
<tr>
<td>High (&gt;10%)</td>
<td>9</td>
<td>32%</td>
</tr>
<tr>
<td>Total</td>
<td>28</td>
<td>100%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>P-value</th>
<th>Chi Square</th>
<th>OR</th>
<th>95 CI</th>
<th>Fisher’s P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Descriptive Statistics</td>
<td>0.6909</td>
<td>0.0029</td>
<td>0.79</td>
<td>0.243-2.556</td>
</tr>
</tbody>
</table>
Table 3. Comparison of Retail Violation Rates (RVRs) for States that Do and Do Not Have High Youth Environmental ENDS Use as Identified by YRBSS

<table>
<thead>
<tr>
<th>Retail Violation Rate (RVR)</th>
<th>High Youth Environmental ENDS Use</th>
<th>Total Number of States</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Number</td>
<td>Percent</td>
</tr>
<tr>
<td>Low (&lt;10%)</td>
<td>11</td>
<td>58%</td>
</tr>
<tr>
<td>High (&gt;10%)</td>
<td>8</td>
<td>42%</td>
</tr>
<tr>
<td>Total</td>
<td>19</td>
<td>100%</td>
</tr>
<tr>
<td>P-value</td>
<td>0.9573</td>
<td>0.1581</td>
</tr>
<tr>
<td>Fisher’s P-Value</td>
<td>0.3049</td>
<td>0.203-4.524</td>
</tr>
</tbody>
</table>

Descriptive Statistics
Table 4. Comparison of Retail Violation Rates (RVRs) for States that Do and Do Not Have High ENDS Retail Availability as Identified by YRBSS

<table>
<thead>
<tr>
<th>Retail Violation Rate (RVR)</th>
<th>High ENDS Retail Availability</th>
<th>Total Number of States</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Low (&lt;10%)</td>
<td>16</td>
<td>8</td>
</tr>
<tr>
<td>High (&gt;10%)</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td>Total</td>
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<td>15</td>
</tr>
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<table>
<thead>
<tr>
<th>P-value</th>
<th>Chi Square</th>
<th>OR</th>
<th>95 CI</th>
<th>Fisher’s P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.9537</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>0.0022</td>
</tr>
</tbody>
</table>

Descriptive Statistics

Table 4 shows the comparison of retail violation rates (RVRs) for states that do and do not have high ENDS retail availability as identified by YRBSS. The table includes the number and percentage of states in each category, along with statistical measures such as the Chi Square and OR, and Fisher’s P-Value.
**Table 5.** Comparison of Retail Violation Rates (RVRs) for States that Do and Do Not Utilize Youth Inspectors Over 18

<table>
<thead>
<tr>
<th>Retail Violation Rate (RVR)</th>
<th>Use of Inspectors over 18</th>
<th>Total Number of States</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Number</td>
<td>Percent</td>
</tr>
<tr>
<td>Low (&lt;10%)</td>
<td>26</td>
<td>70%</td>
</tr>
<tr>
<td>High (&gt;10%)</td>
<td>11</td>
<td>30%</td>
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<tr>
<td>Total</td>
<td>37</td>
<td>100%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>P-value</th>
<th>Chi Square</th>
<th>OR</th>
<th>95 CI</th>
<th>Fisher’s P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Descriptive Statistics</td>
<td>0.4857</td>
<td>0.486</td>
<td>1.61</td>
<td>.423-6.101</td>
<td>0.2097</td>
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</tbody>
</table>
Table 6. Comparison of Retail Violation Rates (RVRs) for States that Do and Do Not Require Youth to Carry ID

<table>
<thead>
<tr>
<th>Retail Violation Rate (RVR)</th>
<th>Carry ID</th>
<th>Total Number of States</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Number</td>
<td>Percent</td>
</tr>
<tr>
<td>Low (&lt;10%)</td>
<td>23</td>
<td>82%</td>
</tr>
<tr>
<td>High (&gt;10%)</td>
<td>5</td>
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<tr>
<td>Total</td>
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<td>100%</td>
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Descriptive Statistics

<table>
<thead>
<tr>
<th></th>
<th>P-value</th>
<th>Chi Square</th>
<th>OR</th>
<th>95 CI</th>
<th>Fisher’s P-Value</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>0.0318</td>
<td>4.6066</td>
<td>3.83</td>
<td>1.124-13.076</td>
<td>0.0227</td>
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</table>
Table 7. Tested Independent Variables for RVR and Statistics for relationship with High RVR

<table>
<thead>
<tr>
<th>Variable</th>
<th>P-value</th>
<th>Chi Square</th>
<th>95 CI</th>
<th>OR</th>
<th>P-Value, Fisher's Exact Test</th>
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<tbody>
<tr>
<td>ENDS included in Inspection Protocol</td>
<td>0.6909</td>
<td>0.1581</td>
<td>.243-2.556</td>
<td>0.79</td>
<td></td>
</tr>
<tr>
<td>High Environmental ENDS use</td>
<td>0.9573</td>
<td>0.0029</td>
<td>.203-4.524</td>
<td>.958</td>
<td>0.3049</td>
</tr>
<tr>
<td>Retail Availability</td>
<td>0.9537</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>0.0022</td>
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<tr>
<td>Inspectors are under 21 years old</td>
<td>0.4857</td>
<td>0.486</td>
<td>.423-6.101</td>
<td>1.61</td>
<td>0.2097</td>
</tr>
<tr>
<td>Inspector is required to carry ID</td>
<td>0.0318</td>
<td>4.6066</td>
<td>1.124-13.076</td>
<td>3.83</td>
<td>0.0227</td>
</tr>
</tbody>
</table>
Table 8. RVR by Selected Variables by State for FY2020 Synar Inspection

<table>
<thead>
<tr>
<th>State</th>
<th>RVR (%)</th>
<th>Retail Availability of ENDS (%)</th>
<th>ENDS Use in State (%)</th>
<th>Use of Under 21 Year Old Inspectors</th>
<th>ENDS Included in Inspections</th>
<th>Youth Inspectors Carry ID</th>
<th>Any Change in Law Regarding Inspections</th>
<th>Other Changes in State Law</th>
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<tbody>
<tr>
<td>AL</td>
<td>4.2%</td>
<td>10.4%</td>
<td>7.5%</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>AK</td>
<td>6.6%</td>
<td>2.1%</td>
<td>6.8%</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>AZ</td>
<td>2%</td>
<td>6.2%</td>
<td>10.1%</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>AR</td>
<td>17.9%</td>
<td>11.6%</td>
<td>3.6%</td>
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<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>CO</td>
<td>8%</td>
<td>9.9%</td>
<td>8.5%</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>CT</td>
<td>9.9%</td>
<td>11.9%</td>
<td>8.5%</td>
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<td>No</td>
<td>No</td>
<td>No</td>
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</tr>
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<td>1.7%</td>
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<td>No</td>
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</tr>
<tr>
<td>DC</td>
<td>4.9%</td>
<td>1.7%</td>
<td></td>
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<td>Yes</td>
<td>No</td>
<td>No</td>
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</tr>
<tr>
<td>FL</td>
<td>7.6%</td>
<td>1.7%</td>
<td></td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>GA</td>
<td>7.7%</td>
<td>14.6%</td>
<td>5.4%</td>
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<tr>
<td>HI</td>
<td>5.7%</td>
<td>4.7%</td>
<td>10.4%</td>
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<td>ID</td>
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<td>8.5%</td>
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<td>No</td>
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<tr>
<td>IL</td>
<td>15.2%</td>
<td>12.9%</td>
<td>8%</td>
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<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>IN</td>
<td>15%</td>
<td>9.1%</td>
<td>8.2%</td>
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Figure 1. Study Design: Specific Aims and High RVR

Specific Aim 1: ENDS Inclusion in Inspection Protocol

Specific Aim 2: States with High ENDS Use or High Retail Availability

Specific Aim 3: Presence of State Regulatory Policies (Including Use of Inspectors Under 21 and Carrying ID)

High RVR
Figure 2. Conceptual Framework: PESTLE and RVR
Figure 3. PESTLE Analysis, with variables studied in bold.
Figure 4. RVR And Inclusion of ENDS in FY2020 Synar Inspections
Figure 5. Data Collection

- Inspectors Trained
  - Inspections Occur
    - Buy
    - No Buy
  - Inspection Data and Cleaned by State
    - Compiled to ASR
      - Submitted to SAMHSA
      - Published by State
Figure 6. RVR and ENDS Use as Indicated by YRBSS.
Figure 7. RVR and Retail Availability as Indicated by YRBSS.
Figure 8. Any Change in Laws Around Inspections as indicated by the FY2020 ASR
Figure 9. Change in Laws and RVR

[Map showing states in different colors indicating changes in laws and RVR]

Legend:
- Blue: Any Change in Law and High RVR
- Yellow: Any Change in Law and Low RVR
- Grey: No Change in Law

Checked with mapchart.net
Figure 10. RVR and Use of Under 21 Year Old Inspectors
Figure 11. RVR and Use of Inspectors that Carry ID.
Figure 12. Conceptual Framework: Conclusions
Appendix A: FFY 2021 ASR
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INTRODUCTION

The Annual Synar Report (ASR) format provides the means for states to comply with the reporting provisions of the Public Health Service Act (42 U.S.C. 300x-26) and the Tobacco Regulation for the Substance Abuse Prevention and Treatment Block Grant (SABG) (45 C.F.R. 96.130 (e)).

How the Synar report helps the Center for Substance Abuse Prevention

In accordance with the tobacco regulations, states are required to provide detailed information on progress made in enforcing youth tobacco access laws (FFY 2020 Compliance Progress) and future plans to ensure compliance with the Synar requirements to reduce youth tobacco access rates (FFY 2021 Intended Use Plan). These data are required by 42 U.S.C. 300x-26 and will be used by the Secretary to evaluate state compliance with the statute. Part of the mission of the Center for Substance Abuse Prevention (CSAP) is to assist states by supporting Synar activities and providing technical assistance helpful in determining the type of enforcement measures and control strategies that are most effective. This information is helpful to CSAP in improving technical assistance resources and expertise on enforcement efforts and tobacco control program support activities, including state Synar program support services, through an enhanced technical assistance program involving conferences and workshops, development of training materials and guidance documents, and onsite technical assistance consultation.

How the Synar report can help states

The information gathered for the Synar report can help states describe and analyze substate needs for program enhancements. These data can also be used to report to the state legislature and other state and local organizations on progress made to date in enforcing youth tobacco access laws when aggregated statistical data from state Synar reports can demonstrate to the Secretary the national progress in reducing youth tobacco access problems. This information will also provide Congress with a better understanding of state progress in implementing Synar, including state difficulties and successes in enforcing retailer compliance with youth tobacco access laws.

Getting assistance in completing the Synar report

If you have questions about programmatic issues, you may call CSAP’s Division of State Programs at (240) 276-2550 and ask for your respective State Project Officer, or contact your State Project Officer directly by telephone or email. If you have questions about fiscal or grants management issues, you may call the Grants Management Officer, Office of Financial Resources, Division of Grants Management, at (240) 276-1422.

Where and when to submit the Synar report

The ASR must be received by SAMHSA no later than December 31, 2020 and must be submitted in the format specified by these instructions. Use of the approved format will avoid delays in the review and approval process. The chief executive officer (or an authorized designee) of the applicant organization must sign page one of the ASR certifying that the state has complied with all reporting requirements.

The state must upload one copy of the ASR using the online WebBGAS (Block Grant Application System). In addition, the following items must be uploaded to WebBGAS:

- FFY 2021 Synar Survey Results: States that use the Synar Survey Estimation System (SSES) must upload one copy of SSES Tables 1–8 (in Excel) to WebBGAS. Please note that, beginning with the FFY 2021 ASR, SSES will generate Tables 6, 7, and 8, which are based on the optional microdata on product type, retail outlet type, and whether identification was requested. If your state does not submit these optional data, Tables 6, 7, and 8 will be blank. Tables 6, 7, and 8 are generated for the convenience of the state, and states are not required to submit completed versions of Tables 6, 7, or 8. States that do not use SSES must upload one copy of ASR Forms 1, 4, and 5, and Forms 2 and 3, if applicable, (in Excel), as well as a database with the raw inspection data to WebBGAS.
- Synar Inspection Form: States must upload one blank copy of the inspection form used to record the result of each Synar inspection.
- Synar Inspection Protocol: States must upload a copy of the protocol used to train inspection teams on conducting and reporting the results of the Synar inspections. This document should be different than the Appendix C attached to the Annual Synar Report.
- A scanned copy of the signed Funding Agreements/Certifications

Each state SSA Director has been emailed a login ID and password to log onto the Synar section of the WebBGAS site.

1The term “state” is used to refer to all the states and territories required to comply with Synar as part of the Substance Abuse Prevention and Treatment Block Grant Program requirements (42 U.S.C. 300x-64 and 45 C.F.R. 96.121).
The following form must be signed by the Chief Executive Officer or an authorized designee and submitted with this application. Documentation authorizing a designee must be attached to the application.

### PUBLIC HEALTH SERVICES ACT AND SYNAR AMENDMENT

42 U.S.C. 300x-26 requires each state to submit an annual report of its progress in meeting the requirements of the Synar Amendment and its implementing regulation (45 C.F.R. 96.130) to the Secretary of the Department of Health and Human Services. By signing below, the chief executive officer (or an authorized designee) of the applicant organization certifies that the state has complied with these reporting requirements and the certifications as set forth below.

**SYNAR SURVEY SAMPLING METHODOLOGY**

The state certifies that the Synar survey sampling methodology on file with the Center for Substance Abuse Prevention and submitted with the Annual Synar Report for FFY 2021 is up-to-date and approved by the Center for Substance Abuse Prevention.

**SYNAR SURVEY INSPECTION PROTOCOL**

The state certifies that the Synar Survey Inspection Protocol on file with the Center for Substance Abuse Prevention and submitted with the Annual Synar Report for FFY 2021 is up-to-date and approved by the Center for Substance Abuse Prevention.

State:

Name of Chief Executive Officer or Designee:

Signature of CEO or Designee:

Title: __________________________ Date Signed: __________________________

If signed by a designee, a copy of the designation must be attached.

### SECTION I: FFY 2020 (Compliance Progress)

**YOUTH ACCESS LAWS, ACTIVITIES, AND ENFORCEMENT**

42 U.S.C. 300x-26 requires the states to report information regarding the sale/distribution of tobacco products to individuals under age 18.

1. Please indicate any changes or additions to the state tobacco statute(s) relating to youth access since the last reporting year. If any changes were made to the state law(s) since the last reporting year, please upload a copy of the state law to WebBGAS. (see 42 U.S.C. 300x-26).

   a. Has there been a change in the minimum sale age for tobacco products?
      - Yes [ ] No [ ]
      - If Yes, current minimum age: [ ] 19 [ ] 20 [ ] 21

   b. Have there been any changes in state law that impact the state’s protocol for conducting Synar inspections?
      - Yes [ ] No [ ]
      - If Yes, indicate change. (Check all that apply.)
        - Changed to require that law enforcement conduct inspections of tobacco outlets
        - Changed to make it illegal for youth to possess, purchase or receive tobacco
        - Changed to require ID to purchase tobacco
        - Changed definition of tobacco products
        - Other change(s) (Please describe.) __________________________

   c. Have there been any changes in state law that impact the following?
      - Licensing of tobacco vendors [ ] Yes [ ] No
      - Penalties for sales to minors [ ] Yes [ ] No
      - Vending machines [ ] Yes [ ] No
      - Added product categories to youth access law [ ] Yes [ ] No

2. Describe how the Annual Synar Report (see 45 C.F.R. 96.130(e)) was made public within the state prior to submission of the ASR. (Check all that apply.)

   - Placed on file for public review
   - Posted on a state agency Web site (Please provide exact Web address and the date when the FFY 2021 ASR was posted to this Web address.)
     - Web address: __________________________
     - Date published: __________________________
   - Notice published in a newspaper or newsletter
   - Public hearing
3. Identify the following agency or agencies (see 42 U.S.C. 300x-26 and 45 C.F.R. 96.130).
   a. The state agency(ies) designated by the Governor for oversight of the Synar requirements:

   Has this changed since last year’s Annual Synar Report?
   □ Yes □ No

   b. The state agency(ies) responsible for conducting random, unannounced Synar inspections:

   Has this changed since last year’s Annual Synar Report?
   □ Yes □ No

   c. The state agency(ies) responsible for enforcing youth tobacco access law(s):

   Has this changed since last year’s Annual Synar Report?
   □ Yes □ No

4. Identify the following agencies and describe their relationship with the agency responsible for the oversight of the Synar requirements.
   a. Identify the state agency responsible for tobacco prevention activities (the agency that receives the Centers for Disease Control and Prevention’s National Tobacco Control Program funding).

   b. Has the responsible agency changed since last year’s Annual Synar Report?
   □ Yes □ No

   c. Describe the coordination and collaboration that occur between the agency responsible for tobacco prevention and the agency responsible for oversight of the Synar requirements. (Check all that apply.) The two agencies
   □ Are the same
   □ Have a formal written memorandum of agreement
   □ Have an informal partnership

   d. Does a state agency contract with the Food and Drug Administration’s Center for Tobacco Products (FDA/CTP) to enforce the youth access and advertising restrictions in the Family Smoking Prevention and Tobacco Control Act? □ Yes □ No (if no, go to Question 5)

   e. If yes, identify the state agency responsible for enforcing the youth access and advertising restrictions in the Family Smoking Prevention and Tobacco Control Act (the agency that is under contract to the Food and Drug Administration’s Center for Tobacco Products (FDA/CTP)).

   f. Has the responsible agency changed since last year’s Annual Synar Report?
   □ Yes □ No

   g. Describe the coordination and collaboration that occur between the agency contracted with the FDA to enforce federal youth tobacco access laws and the agency responsible for oversight of the Synar requirements. (Check all that apply.) The two agencies:
   □ Are the same
   □ Have a formal written memorandum of agreement
   □ Have an informal partnership
   □ Conduct joint planning activities
   □ Combine resources
   □ Have other collaborative arrangement(s) (Please describe.)
   □ No relationship

   h. Does the state use data from the FDA enforcement inspections for Synar survey reporting?
   □ Yes □ No
5. Please answer the following questions regarding the state’s activities to enforce the state’s youth access to tobacco law(s) in FFY 2020 (see 42 U.S.C. 300x-26 and 45 C.F.R. 96.130(e)).

a. Which one of the following describes the enforcement of state youth access to tobacco laws carried out in your state? (Check one category only.)
   - [ ] Enforcement is conducted exclusively by local law enforcement agencies.
   - [ ] Enforcement is conducted exclusively by state agency(ies).
   - [ ] Enforcement is conducted by both local and state agencies.

b. The following items concern penalties imposed for all violations of state youth access to tobacco laws by LOCAL AND/OR STATE LAW ENFORCEMENT AGENCIES (this does not include enforcement of local laws or federal youth tobacco access laws). Please fill in the number requested. If state law does not allow for an item, please mark “NA” (not applicable). If a response for an item is unknown, please mark “UNK.” The chart must be filled in completely.

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</table>

c. Are citations or warnings issued to retailers or clerks who sell tobacco to minors for inspections that are part of the Synar survey?
   - [ ] Yes  [ ] No
   
   If “Yes” to 5c, please describe the state’s procedure for minimizing risk of bias to the survey results from retailers alerting each other to the presence of the survey teams:

   

d. Which one of the following best describes the level of enforcement of state youth access to tobacco laws carried out in your state? (Check one category only.)
   - [ ] Enforcement is conducted only at those outlets randomly selected for the Synar survey.
   - [ ] Enforcement is conducted only at a subset of outlets not randomly selected for the Synar survey.
   - [ ] Enforcement is conducted at a combination of outlets randomly selected for the Synar survey and outlets not randomly selected for the Synar survey.

e. Did every tobacco outlet in the state receive at least one compliance check that included enforcement of the state youth tobacco access law(s) in the last year?
   - [ ] Yes  [ ] No

f. What additional activities are conducted in your state to support enforcement and compliance with state youth tobacco access law(s)? (Check all that apply and briefly describe each activity in the text boxes below each activity.)
   - [ ] Merchant education and/or training

   

5

6
SYNAR SURVEY METHODS AND RESULTS

The following questions pertain to the survey methodology and results of the Synar survey used by the state to meet the requirements of the Synar Regulation in FFY 2020 (see 42 U.S.C. 300x-26 and 45 C.F.R. 96.130).

6. Has the sampling methodology changed from the previous year?
   □ Yes  □ No

   The state is required to have an approved up-to-date description of the Synar sampling methodology on file with CSAP. Please submit a copy of your Synar Survey Sampling Methodology (Appendix B). If the sampling methodology changed from the previous reporting year, these changes must be reflected in the methodology submitted.

   a. If yes, describe how and when this change was communicated to SAMHSA

7. Please answer the following questions regarding the state’s annual random, unannounced inspections of tobacco outlets (see 45 C.F.R. 96.130(d)(2)).

   a. Did the state use the optional Synar Survey Estimation System (SSES) to analyze the Synar survey data?
      □ Yes  □ No

      If Yes, upload a copy of SSES tables 1–8 (in Excel) to WebBGAS. Then go to Question 8. If No, continue to Question 7b.

   b. Report the weighted and unweighted Retailer Violation Rate (RVR) estimates, the standard error, accuracy rate (number of eligible outlets divided by the total number of sampled outlets), and completion rate (number of eligible outlets inspected divided by the total number of eligible outlets).

      Unweighted RVR
      Weighted RVR
      Standard error (s.e.) of the (weighted) RVR

      Fill in the blanks to calculate the right limit of the right-sided 95% confidence interval.

      \[
      \text{RVR Estimate} + (1.645 \times \text{Standard Error}) = \text{Right Limit}
      \]

      Accuracy rate
      Completion rate
c. Fill out Form 1 in Appendix A (Forms 1–5). (Required regardless of the sample design.)

d. How were the (weighted) RVR estimate and its standard error obtained?
(Check the one that applies.)
- Form 2 (Optional) in Appendix A (Forms 1–5) (Attach completed Form 2.)
- Other (Please specify. Provide formulas and calculations or attach and explain the program code and output with description of all variable names.)

e. If stratification was used, did any strata in the sample contain only one outlet or cluster this year?
- Yes
- No
- No stratification
If Yes, explain how this situation was dealt with in variance estimation.

f. Was a cluster sample design used?
- Yes
- No
If Yes, fill out and attach Form 3 in Appendix A (Forms 1–5), and answer the following question.
If No, go to Question 7g.

Were any certainty primary sampling units selected this year?
- Yes
- No
If Yes, explain how the certainty clusters were dealt with in variance estimation.

g. Report the following outlet sample sizes for the Synar survey.

<table>
<thead>
<tr>
<th>Sample Size</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Effective sample size (sample size needed to meet the SAMHSA precision requirement assuming simple random sampling)</td>
<td></td>
</tr>
<tr>
<td>Target sample size (the product of the effective sample size and the design effect)</td>
<td></td>
</tr>
<tr>
<td>Original sample size (inflated sample size of the target sample to counter the sample attrition due to ineligibility and noncompletion)</td>
<td></td>
</tr>
<tr>
<td>Eligible sample size (number of outlets found to be eligible in the sample)</td>
<td></td>
</tr>
<tr>
<td>Final sample size (number of eligible outlets in the sample for which an inspection was completed)</td>
<td></td>
</tr>
</tbody>
</table>

h. Fill out Form 4 in Appendix A (Forms 1–5).

8. Did the state’s Synar survey use a list frame?
- Yes
- No
If Yes, answer the following questions about its coverage.

   a. The calendar year of the latest Sampling frame coverage study: ___________

   b. Percent coverage from the latest Sampling frame coverage study: ___________

   c. Was a new study conducted in this reporting period?
   - Yes
   - No
   If Yes, please complete Appendix D (List Sampling Frame Coverage Study) and submit it with the Annual Synar Report.

   d. The calendar year of the next coverage study planned: ________________

9. Has the Synar survey inspection protocol changed from the previous year?
- Yes
- No
The state is required to have an approved up-to-date description of the Synar inspection protocol on file with CSAP. Please submit a copy of your Synar Survey Inspection Protocol (Appendix C). If the inspection protocol changed from the previous year, these changes must be reflected in the protocol submitted.

   a. If Yes, describe how and when this change was communicated to SAMHSA

   b. Provide the inspection period: From ___________ to ___________

   c. Provide the number of youth inspectors used in the current inspection year:


NOTE: If the state uses SSES, please ensure that the number reported in 9b matches that reported in SSES Table 4, or explain any difference.

d. Fill out and attach Form 5 in Appendix A (Forms 1–5). (Not required if the state used SSES to analyze the Synar survey data.)
SECTION II: FFY 2021 (Intended Use):

Public Law 42 U.S.C. 300x-26 of the Public Health Service Act and 45 C.F.R. 96.130 (c) (4, 5) require that the states provide information on future plans to ensure compliance with the Synar requirements to reduce youth tobacco access.

1. In the upcoming year, does the state anticipate any changes in:
   - Synar sampling methodology [ ] Yes [ ] No
   - Synar inspection protocol [ ] Yes [ ] No

   If changes are made in either the Synar sampling methodology or the Synar inspection protocol, the state is required to obtain approval from CSAP prior to implementation of the change and file an updated Synar Survey Sampling Methodology (Appendix B) or an updated Synar Survey Inspection Protocol (Appendix C), as appropriate.

2. Please describe the state’s plans to maintain and/or reduce the target rate for Synar inspections to be completed in FFY 2021. Include a brief description of plans for law enforcement efforts to enforce youth tobacco access laws, activities that support law enforcement efforts to enforce youth tobacco access laws, and any anticipated changes in youth tobacco access legislation or regulation in the state.

3. Describe any challenges the state faces in complying with the Synar regulation. (Check all that apply and describe each challenge in the text box below it.)

   - [ ] Limited resources for law enforcement of youth access laws
   - [ ] Limited resources for activities to support enforcement and compliance with youth tobacco access laws
   - [ ] Limitations in the state youth tobacco access laws
   - [ ] Limited public support for enforcement of youth tobacco access laws
   - [ ] Limitations on completeness/accuracy of list of tobacco outlets
   - [ ] Limited expertise in survey methodology
   - [ ] Laws/regulations limiting the use of minors in tobacco inspections
   - [ ] Difficulties recruiting youth inspectors
   - [ ] Issues regarding the balance of inspections conducted by youth inspectors age 15 and under
   - [ ] Issues regarding the balance of inspections conducted by one gender of youth inspectors
   - [ ] Geographic, demographic, and logistical considerations in conducting inspections
   - [ ] Cultural factors (e.g., language barriers, young people purchasing for their elders)
   - [ ] Issues regarding sources of tobacco under tribal jurisdiction
   - [ ] Other challenges (Please list.)
APPENDIX A: FORMS 1–5

FORM 1 (Required for all states not using the Synar Survey Estimation System [SSES] to analyze the Synar Survey data)

Complete Form 1 to report sampling frame and sample information and to calculate the unweighted retailer violation rate (RVR) using results from the current year’s Synar survey inspections.

**Instructions for Completing Form 1:** In the top right-hand corner of the form, provide the state name and reporting federal fiscal year (FFY 2021). Provide the remaining information by stratum if stratification was used. Make copies of the form if additional rows are needed to list all the strata.

**Column 1:** If stratification was used:
- 1(a) Sequentially number each row.
- 1(b) Write in the name of each stratum. All strata in the state must be listed.

If no stratification was used:
- 1(a) Leave blank.
- 1(b) Write “state” in the first row (indicates that the whole state is a single stratum).

Note for unstratified samples: For Columns 2–5, wherever the instruction refers to “each stratum,” report the specified information for the state as a whole.

**Column 2:**
- 2(a) Report the number of over-the-counter (OTC) outlets in the sampling frame in each stratum.
- 2(b) Report the number of vending machine (VM) outlets in the sampling frame in each stratum.
- 2(c) Report the combined total of OTC and VM outlets in the sampling frame in each stratum.

**Column 3:**
- 3(a) Report the estimated number of eligible OTC outlets in the OTC outlet population in each stratum.
- 3(b) Report the estimated number of eligible VM outlets in the VM outlet population in each stratum.
- 3(c) Report the combined total estimated number of eligible OTC and VM outlets in the total outlet population in each stratum.

The estimates for Column 3 can be obtained from the Synar survey sample as the weighted sum of eligible outlets by outlet type.

**Column 4:**
- 4(a) Report the number of eligible OTC outlets for which an inspection was completed, for each stratum.
- 4(b) Report the numbers of eligible VM outlets for which an inspection was completed, for each stratum.
- 4(c) Report the combined total of eligible OTC and VM outlets for which an inspection was completed, for each stratum.

**Column 5:**
- 5(a) Report the number of OTC outlets found in violation of the law as a result of completed inspections, for each stratum.
- 5(b) Report the number of VM outlets found in violation of the law as a result of completed inspections, for each stratum.
- 5(c) Report the combined total of OTC and VM outlets found in violation of the law as a result of completed inspections, for each stratum.

**Totals:** For each subcolumn (a–c) in Columns 2–5, provide totals for the state as a whole in the last row of the table. Those numbers will be the sum of the numbers in each row for the respective column.

<table>
<thead>
<tr>
<th>STRATUM</th>
<th>NUMBER OF OUTLETS IN SAMPLING FRAME</th>
<th>ESTIMATED NUMBER OF ELIGIBLE OUTLETS IN POPULATION</th>
<th>NUMBER OF OUTLETS INSPECTED</th>
<th>NO. OF OUTLETS FOUND IN VIOLATION DURING INSPECTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1)</td>
<td>(2)</td>
<td>(3)</td>
<td>(4)</td>
<td>(5)</td>
</tr>
<tr>
<td>(a)</td>
<td>(b) Stratum Name</td>
<td>(c) OTC Outs (OTC)</td>
<td>(d) VM Outs (VM)</td>
<td>(e) Total Outs (OTC + VM)</td>
</tr>
<tr>
<td></td>
<td>(f) OTC Outs (OTC)</td>
<td>(g) VM Outs (VM)</td>
<td>(h) Total Outs (OTC + VM)</td>
<td>(i) Total Outs (OTC + VM)</td>
</tr>
<tr>
<td></td>
<td>(j) OTC Outs (OTC)</td>
<td>(k) VM Outs (VM)</td>
<td>(l) Total Outs (OTC + VM)</td>
<td>(m) Total Outs (OTC + VM)</td>
</tr>
</tbody>
</table>

**Summary of Synar Inspection Results by Stratum**

State: FFY: 2021

RECORD COLUMN TOTALS ON LAST LINE (LAST PAGE ONLY IF MULTIPLE PAGES ARE NEEDED).
**FORM 2 (Optional)**  
Appropriate for stratified simple or systematic random sampling designs.

Complete Form 2 to calculate the weighted RVR. This table (in Excel form) is designed to calculate the weighted RVR for stratified simple or systematic random sampling designs, accounting for ineligible outlets and noncomplete inspections encountered during the annual Synar survey.

**Instructions for Completing Form 2:** In the top right-hand corner of the form, provide the state name and reporting federal fiscal year (FFY 2021).

| Column 1: Write in the name of each stratum into which the sample was divided. These should match the strata reported in Column 1(b) of Form 1. |
| Column 2: Report the number of outlets in the sampling frame in each stratum. These numbers should match the numbers reported for the respective strata in Column 2(c) of Form 1. |
| Column 3: Report the original sample size (the number of outlets originally selected, including substitutes or replacements) for each stratum. |
| Column 4: Report the number of sample outlets in each stratum that were found to be eligible during the inspections. Note that this number must be less than or equal to the number reported in Column 3 for the respective strata. |
| Column 5: Report the number of eligible outlets in each stratum for which an inspection was completed. Note that this number must be less than or equal to the number reported in Column 4 for the respective strata. |
| Column 6: Report the number of eligible outlets inspected in each stratum that were found in violation. These numbers should match the numbers reported in Column 5(c) of Form 1 for the stratum. |

**Column 7:** Form 2 (in Excel form) will automatically calculate the stratum RVR for each stratum in this column. This is calculated by dividing the number of inspected eligible outlets found in violation (Column 6) by the number of inspected eligible outlets (Column 5). The state unweighted RVR will be shown in the Total row of Column 7.

**Column 8:** Form 2 (in Excel form) will automatically calculate the estimated number of eligible outlets in the population for each stratum. This calculation is made by multiplying the number of outlets in the sampling frame (Column 2) times the number of eligible outlets (Column 4) divided by the original sample size (Column 3). These numbers should be less than or equal to the numbers in Column 2.

**Column 9:** Form 2 (in Excel form) automatically calculates the relative stratum weight by dividing the estimated number of eligible outlets in the population for each stratum in Column 8 by the Total of the values in Column 8.

**Column 10:** Form 2 (in Excel form) will automatically calculate each stratum’s contribution to the state weighted RVR by multiplying the stratum RVR (Column 7) by the relative stratum weight (Column 9). The weighted RVR for the state will be shown in the Total row of Column 10.

**Column 11:** Form 2 (in Excel form) automatically calculates the standard error of each stratum’s RVR (Column 7). The standard error for the state weighted RVR will be shown in the Total row of Column 11.

**TOTAL:** For Columns 2–6, Form 2 (in Excel form) provides totals for the state as a whole in the last row of the table. For Columns 7–11, it calculates the respective statistic for the state as a whole.

<table>
<thead>
<tr>
<th>Calculation of Weighted Retailer Violation Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>State: FFY 2021</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>(1) Stratum Name</th>
<th>(2) Number of Outlets in Sampling Frame</th>
<th>(3) Original Sample Size</th>
<th>(4) Number of Outlets Found Eligible</th>
<th>(5) Number of Outlets Inspected</th>
<th>(6) Number of Outlets Found in Violation</th>
<th>(7) ( p = \frac{x}{n2} ) Stratum Retailer Violation Rate</th>
<th>(8) ( N' = N \frac{n1}{n} ) Estimated Number of Eligible Outlets in Population</th>
<th>(9) ( w = \frac{N'}{\text{Total of Column 8}} ) Relative Stratum Weight</th>
<th>(10) ( pw ) Stratum Contribution to State Weighted RVR</th>
<th>(11) ( s.e. ) Standard Error of Stratum RVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>N - number of outlets in sampling frame</td>
<td></td>
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<tr>
<td>n - original sample size (number of outlets in the original sample)</td>
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<td>n1 - number of sample outlets that were found to be eligible</td>
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<td>n2 - number of eligible outlets that were inspected</td>
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<tr>
<td>x - number of inspected outlets that were found in violation</td>
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<tr>
<td>p - stratum retailer violation rate (p=x/n2)</td>
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</tr>
<tr>
<td>N' - estimated number of eligible outlets in population (N'=N*n1/n)</td>
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<tr>
<td>w - relative stratum weight (w=N'/Total Column 8)</td>
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<tr>
<td>pw - stratum contribution to the weighted RVR</td>
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<tr>
<td>s.e. - standard error of the stratum RVR</td>
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</tr>
</tbody>
</table>

15
FORM 3 (Required when a cluster design is used for all states not using the Synar Survey Estimation System [SSES] to analyze the Synar survey data.)

Complete Form 3 to report information about primary sampling units when a cluster design was used for the Synar survey.

**Instructions for Completing Form 3:** In the top right-hand corner of the form, provide the state name and reporting federal fiscal year (FFY 2021).

Provide information by stratum if stratification was used. Make copies of the form if additional rows are needed to list all the strata.

1. **Column 1:** Sequentially number each row.
2. **Column 2:** If stratification was used: Write in the name of stratum. All strata in the state must be listed.
   - If no stratification was used: Write “state” in the first row to indicate that the whole state constitutes a single stratum.
3. **Column 3:** Report the number of primary sampling units (PSUs) (i.e., first-stage clusters) created for each stratum.
4. **Column 4:** Report the number of PSUs selected in the original sample for each stratum.
5. **Column 5:** Report the number of PSUs in the final sample for each stratum.

**TOTALS:** For Columns 3–5, provide totals for the state as a whole in the last row of the table.

### Summary of Clusters Created and Sampled

<table>
<thead>
<tr>
<th>(1) Row #</th>
<th>(2) Stratum Name</th>
<th>(3) Number of PSUs Created</th>
<th>(4) Number of PSUs Selected</th>
<th>(5) Number of PSUs in the Final Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

| TOTAL     |                  |                            |                             |                                       |

**FORM 4 (Required for all states not using the Synar Survey Estimation System [SSES] to analyze the Synar Survey data)**

Complete Form 4 to provide detailed tallies of ineligible sample outlets by reasons for ineligibility and detailed tallies of eligible sample outlets with noncomplete inspections by reasons for noncompletion.

**Instructions for Completing Form 4:** In the top right-hand corner of the form, provide the state name and reporting federal fiscal year (FFY 2021).

1. **Column 1(a):** Enter the number of sample outlets found ineligible for inspection by reason for ineligibility. Provide the total number of ineligible outlets in the row marked “Total.”
2. **Column 2(a):** Enter the number of eligible sample outlets with noncomplete inspections by reason for noncompletion. Provide the total number of eligible outlets with noncomplete inspections in the row marked “Total.”

### Inspection Tallies by Reason of Ineligibility or Noncompletion

<table>
<thead>
<tr>
<th>Reason for Ineligibility</th>
<th>(a) Counts</th>
<th>Reason for Noncompletion</th>
<th>(a) Counts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Out of business</td>
<td></td>
<td>In operation but closed at time of visit</td>
<td></td>
</tr>
<tr>
<td>Does not sell tobacco products</td>
<td></td>
<td>Unsafe to access</td>
<td></td>
</tr>
<tr>
<td>Inaccessible by youth</td>
<td></td>
<td>Presence of police</td>
<td></td>
</tr>
<tr>
<td>Private club or private residence</td>
<td></td>
<td>Youth inspector knows salesperson</td>
<td></td>
</tr>
<tr>
<td>Temporary closure</td>
<td></td>
<td>Moved to new location</td>
<td></td>
</tr>
<tr>
<td>Unlocatable</td>
<td></td>
<td>Drive-thru only/youth inspector has no driver’s license</td>
<td></td>
</tr>
<tr>
<td>Wholesale only/Carton sale only</td>
<td></td>
<td>Tobacco out of stock</td>
<td></td>
</tr>
<tr>
<td>Vending machine broken</td>
<td></td>
<td>Ran out of time</td>
<td></td>
</tr>
<tr>
<td>Duplicate</td>
<td></td>
<td>Other noncompletion reason(s) (Describe)</td>
<td></td>
</tr>
<tr>
<td>Other ineligibility reason(s) (Describe)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| TOTAL | | TOTAL | |
**FORM 5 (Required for all states not using the Synar Survey Estimation System [SSES] to analyze the Synar survey data)**

Complete Form 5 to show the distribution of outlet inspection results by age and gender of the youth inspectors.

**Instructions for Completing Form 5:** In the top right-hand corner of the form, provide the state name and reporting federal fiscal year (FFY 2021).

Column 1: Enter the number of attempted buys by youth inspector age and gender.

Column 2: Enter the number of successful buys by youth inspector age and gender.

If the inspectors are age eligible but the gender of the inspector is unknown, include those inspections in the “Other” row. Calculate subtotals for males and females in rows marked “Male Subtotal” and “Female Subtotal.” Sum subtotals for Male, Female, and Other and record in the bottom row marked “Total.” Verify that the total of attempted buys and successful buys equals the total for Column 4(c) and Column 5(c), respectively, on Form 1. If the totals do not match, please explain any discrepancies.

### Synar Survey Inspector Characteristics

<table>
<thead>
<tr>
<th>State: FFY: 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male Subtotal</td>
</tr>
<tr>
<td>Female Subtotal</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Male</th>
<th>Attempted Buys</th>
<th>Successful Buys</th>
</tr>
</thead>
<tbody>
<tr>
<td>15 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>16 years</td>
<td></td>
<td></td>
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<tr>
<td>17 years</td>
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<tr>
<td>18 years</td>
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<tr>
<td>19 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20 years</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Female</th>
<th>Attempted Buys</th>
<th>Successful Buys</th>
</tr>
</thead>
<tbody>
<tr>
<td>15 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>16 years</td>
<td></td>
<td></td>
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<td>17 years</td>
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<td>18 years</td>
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<td>19 years</td>
<td></td>
<td></td>
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<tr>
<td>20 years</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**APPENDIXES B & C: FORMS**

**Instructions**

Appendix B (Sampling Design) and Appendix C (Inspection Protocol) are to reflect the state’s CSAP-approved sampling design and inspection protocol. These appendixes, therefore, should generally describe the design and protocol and, with the exception of Question #10 of Appendix B, are not to be modified with year-specific information. Please note that any changes to either appendix must receive CSAP’s advance, written approval. To facilitate the state’s completion of this section, simply cut and paste the previously approved sampling design (Appendix B) and inspection protocol (Appendix C) and respond to Question #10 of Appendix B to provide the requested information about sample size calculations for the Synar survey conducted in FFY 2020.
APPENDIX B: SYNAR SURVEY SAMPLING METHODOLOGY

State:  
FFY: 2021

1. What type of sampling frame is used?
   - List frame (Go to Question 2.)
   - Area frame (Go to Question 3.)
   - List-assisted area frame (Go to Question 2.)

2. List all sources of the list frame. Indicate the type of source from the list below. Provide a brief description of the frame source. Explain how the lists are updated (cycle), including how new outlets are identified and added to the frame. In addition, explain how often the lists are updated (cycle). (After completing this question, go to Question 4.)

   Use the corresponding number to indicate Type of Source in the table below.

<table>
<thead>
<tr>
<th>Name of Frame Source</th>
<th>Type of Source</th>
<th>Description</th>
<th>Updating Method and Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 – Statewide commercial business list</td>
<td>1 – Statewide commercial business list</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 – Local commercial business list</td>
<td>2 – Local commercial business list</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 – Statewide tobacco license/permit list</td>
<td>3 – Statewide tobacco license/permit list</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 – Statewide retail license/permit list</td>
<td>4 – Statewide retail license/permit list</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 – Statewide liquor license/permit list</td>
<td>5 – Statewide liquor license/permit list</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 – Other</td>
<td>6 – Other</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. If an area frame is used, describe how area sampling units are defined and formed.

   a. Is any area left out in the formation of the area frame?
      - Yes  
      - No

      If Yes, what percentage of the state’s population is not covered by the area frame?

      %

4. Federal regulation requires that vending machines be inspected as part of the Synar survey. Are vending machines included in the Synar survey?
   - Yes  
   - No

   If No, please indicate the reason(s) they are not included in the Synar survey. Please check all that apply.
   - State law bans vending machines.
   - State law bans vending machines from locations accessible to youth.

5. Which category below best describes the sample design? (Check one.)
   - Census (STOP HERE. Appendix B is complete.)

   Unstratified statewide sample:
   - Simple random sample (Go to Question 9.)
   - Systematic random sample (Go to Question 6.)
   - Single-stage cluster sample (Go to Question 8.)
   - Multistage cluster sample (Go to Question 8.)

   Stratified sample:
   - Simple random sample (Go to Question 7.)
   - Systematic random sample (Go to Question 6.)
   - Single-stage cluster sample (Go to Question 7.)
   - Multistage cluster sample (Go to Question 7.)
   - Other (Please describe and go to Question 9.)

6. Describe the systematic sampling methods. (After completing Question 6, go to Question 7 if stratification is used. Otherwise go to Question 9.)

7. Provide the following information about stratification.
   a. Provide a full description of the strata that are created.

   b. Is clustering used within the stratified sample?
      - Yes (Go to Question 8.)
      - No (Go to Question 9.)
8. Provide the following information about clustering.
   a. Provide a full description of how clusters are formed. (If multistage clusters are used, give definitions of clusters at each stage.)

   b. Specify the sampling method (simple random, systematic, or probability proportional to size sampling) for each stage of sampling and describe how the method(s) is (are) implemented.

9. Provide the following information about determining the Synar Sample.
   a. Was the Synar Survey Estimation System (SSES) used to calculate the sample size?
      - Yes  (Respond to part b.)
      - No   (Respond to part c and Question 10c.)

   b. SSES Sample Size Calculator used?
      - State Level  (Respond to Question 10a.)
      - Stratum Level (Respond to Question 10a and 10b.)

   c. Provide the formulas for determining the effective, target, and original outlet sample sizes.

10. Provide the following information about sample size calculations for the Synar survey conducted in FFY 2020.
    a. If the state uses the sample size formulas embedded in the SSES Sample Size Calculator to calculate the state level sample size, please provide the following information:
       Inputs for Effective Sample Size:
       - RVR:
       - Frame Size:

       Input for Target Sample Size:
       - Design Effect:

       Inputs for Original Sample Size:
       - Safety Margin:
       - Accuracy (Eligibility) Rate:
       - Completion Rate:

    b. If the state uses the sample size formulas embedded in the SSES Sample Size Calculator to calculate the stratum level sample sizes, please provide the stratum level information:

    c. If the state does not use the sample size formulas embedded in the SSES Sample Size Calculator, please provide all inputs required to calculate the effective, target, and original sample sizes as indicated in Question 9.
APPENDIX C: SYNA ROT SURVEY INSPECTION PROTOCOL SUMMARY

State: ____________________________
FFY: 2021

Note: Upload to WebBGAS a copy of the Synar inspection form under the heading “Synar Inspection Form” and a copy of the protocol used to train inspection teams on conducting and reporting the results of the Synar inspections under the heading “Synar Inspection Protocol.”

1. How does the state Synar survey protocol address the following?
   a. Consummated buy attempts?
      ■ Required
      ■ Permitted under specified circumstances (Describe:  )
      ■ Not permitted

   b. Youth inspectors to carry ID?
      ■ Required
      ■ Permitted under specified circumstances (Describe:  )
      ■ Not permitted

   c. Adult inspectors to enter the outlet?
      ■ Required
      ■ Permitted under specified circumstances (Describe:  )
      ■ Not permitted

   d. Youth inspectors to be compensated?
      ■ Required
      ■ Permitted under specified circumstances (Describe:  )
      ■ Not permitted

2. Identify the agency(ies) or entity(ies) that actually conduct the random, unannounced Synar inspections of tobacco outlets. (Check all that apply.)
   ■ Law enforcement agency(ies)
   ■ State or local government agency(ies) other than law enforcement
   ■ Private contractor(s)
   ■ Other
   List the agency name(s):

3. Are Synar inspections combined with law enforcement efforts (i.e., do law enforcement representatives issue warnings or citations to retailers found in violation of the law at the time of the inspection)?
   ■ Always  ■ Usually  ■ Sometimes  ■ Rarely  ■ Never

4. Describe the type of tobacco products that are requested during Synar inspections.
   a. What type of tobacco products are requested during the inspection?
      ■ Cigarettes
      ■ Small Cigars
      ■ Cigarillos
      ■ Smokeless Tobacco
      ■ Electronic Cigarettes/Electronic Nicotine Delivery Systems (ENDS)
      ■ Other

   b. Describe the protocol for identifying what types of products and what brands of products are requested during an inspection.

5a. Describe the methods used to recruit, select, and train adult supervisors.

5b. Describe the methods used to recruit, select, and train youth inspectors.

6. Are there specific legal or procedural requirements instituted by the state to address the issue of youth inspectors’ immunity when conducting inspections?
   a. Legal
      ■ Yes  ■ No
      (If Yes, please describe.)

   b. Procedural
      ■ Yes  ■ No
      (If Yes, please describe.)

7. Are there specific legal or procedural requirements instituted by the state to address the issue of the safety of youth inspectors during all aspects of the Synar inspection process?
   a. Legal
APPENDIX D: LIST SAMPLING FRAME COVERAGE STUDY

(State: 
FFY: 2021)

1. Calendar year of the coverage study: ______

2. a. Unweighted percent coverage found: _____ %
   b. Weighted percent coverage found: _____ %
   c. Number of outlets found through canvassing: ______
   d. Number of outlets matched on the list frame: ______

3. a. Describe how areas were defined. (e.g., census tracts, counties, etc.)
   b. Were any areas of the state excluded from sampling?
      □ Yes □ No
      If Yes, please explain.

4. Please answer the following questions about the selection of canvassing areas.
   a. Which category below best describes the sample design? (Check only one.)
      □ Census (Go to Question 6.)
      Unstratified statewide sample:
      □ Simple random sample (Respond to Part b.)
      □ Systematic random sample (Respond to Part b.)
      □ Single-stage cluster sample (Respond to Parts b and d.)
      □ Multistage cluster sample (Respond to Parts b and d.)
      Stratified sample:
      □ Simple random sample (Respond to Parts b and c.)
      □ Systematic random sample (Respond to Parts b and c.)
      □ Single-stage cluster sample (Respond to Parts b, c, and d.)
      □ Multistage cluster sample (Respond to Parts b, c, and d.)
      □ Other (Please describe and respond to Part b.) ______
   b. Describe the sampling methods.
c. Provide a full description of the strata that were created. 

d. Provide a full description of how clusters were formed.

5. Were borders of the selected areas clearly identified at the time of canvassing?  
☐ Yes  ☐ No

6. Were all sampled areas visited by canvassing teams?  
☐ Yes (Go to Question 7.)  ☐ No (Respond to Parts a and b.)
   a. Was the subset of areas randomly chosen?  
      ☐ Yes  ☐ No
   b. Describe how the subsample of visited areas was drawn. Include the number of areas sampled and the number of areas canvassed.

7. Were field observers provided with a detailed map of the canvassing areas?  
☐ Yes  ☐ No
   If No, describe the canvassing instructions given to the field observers.

8. Were field observers instructed to find all outlets in the assigned area?  
☐ Yes  ☐ No
   If No, respond to Question 9.
   If Yes, describe any instructions given to the field observers to ensure the entire area was canvassed, then go to Question 10.

9. If a full canvassing was not conducted:
   a. How many predetermined outlets were to be observed in each area? _____
   b. What were the starting points for each area? _____
   c. Were these starting points randomly chosen?  
      ☐ Yes  ☐ No
   d. Describe the selection of the starting points.

10. Describe the process field observers used to determine if an outlet sold tobacco.

11. Please provide the state’s definition of “matches” or “mismatches” to the Synar sampling frame? (i.e., address, business name, business license number, etc.)

12. Provide the calculation of the weighted percent coverage (if applicable).