ANNUAL SYNAR REPORT

42 U.S.C. 300x-26 OMB No. 0930-0222

FFY 2020 State: NC

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OMB No. 0930-0222

Expiration Date: 05/31/2022

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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 2019 Compliance Progress) and future plans to ensure compliance with the Synar requirements to reduce youth tobacco access rates (FFY 2020 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. The information to be reported is public (45 CFR 96.130 (f)) and is not confidential. 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.

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).

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, 2019, 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 2020 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 2019 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.

FFY 2020: FUNDING AGREEMENTS/CERTIFICATIONS

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 2020 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 2020 is up-to-date and approved by the

Center for Substance Abuse Prevention.				Ī
State: NC				Ì
Name of Chief Executive Officer or Designee: Deputy Sec Behavioral	retary Health & IDD			
Signature of CEO or Designee:				
Title: Deputy Secretary	Date Signed:	11/1/2019 7	7:44 PM	ED
If signed by a designee, a copy of the desig	 gnation must be att	ached.		Ì

FFY: 2020 State: North Carolina

SECTION I: FFY 2019 (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.	access si the last	ndicate any changes or additions to the state tobacco statute(s) relating to youth ince the last reporting year. If any changes were made to the state law(s) since reporting year, please upload a copy of the state law to WebBGAS. (see 42 00x-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 Other (Please specify.)
	b.	Have there been any changes in state law that impact the state's protocol for conducting <i>Synar inspections?</i>
		☐ 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
		Penalties for sales to minors Vending machines Added product Yes No No
		categories to youth access law Yes No
2.		e how the Annual Synar Report (see 45 C.F.R. 96.130(e)) was made public he 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 en the FFY 2020 ASR was posted to this Web address.)
		<u>Web address:</u> https://www.ncdhhs.gov/divisions/mental-health-developmental-disabilities-and-substance-abuse/reports/annual-synar-report
		Date published:
		Notice published in a newspaper or newsletter

		Public hearing Announced in a news release, a press conference, or discussed in a media interview Distributed for review as part of the SABG application process Distributed through the public library system Published in an annual register
		Other (Please describe.)
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:
		NC Department of Health and Human Services, Division of Mental Health Developmental Disabilities and Substance Abuse Services
		Has this changed since last year's Annual Synar Report?
		☐ Yes ⊠ No
	b.	The state agency(ies) responsible for conducting random, unannounced Synar inspections:
		NC Department of Public Safety, State Bureau of Investigation, Alcohol Law Enforcement Branch (ALE)
		Has this changed since last year's Annual Synar Report?
		∑ Yes
	c.	The state agency(ies) responsible for enforcing youth tobacco access law(s):
		NC Department of Public Safety, State Bureau of Investigation, Alcohol Law Enforcement Branch
		Has this changed since last year's Annual Synar Report?
		☐ Yes ⊠ No
4.	-	the following agencies and describe their relationship with the agency ible 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).
		NC Department of Health and Human Services, Division of Public Health, Tobacco Prevention and Control Branch
	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
	Conduct joint planning activities
	Combine resources
	Have other collaborative arrangement(s) (<i>Please describe</i> .)
	☐ No relationship
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)).
	NC Department of Health and Human Services, Division of Mental Health Developmental Disabilities and Substance Abuse Services
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) (<i>Please describe</i> .)
	☐ 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 2019 (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 <i>and</i> state agencies.				

b. The following items concern penalties imposed for all violations of state youth access to tobacco laws by <u>LOCAL AND/OR STATE LAW ENFORCEMENT AGENCIES</u> (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.

PENALTY	OWNERS	CLERKS	TOTAL
Number of citations issued	NA	52	52
Number of fines assessed	NA	UNK	UNK
Number of permits/licenses suspended	NA		NA
Number of permits/licenses revoked	NA		NA
Other: Signage not posted	7	0	7

Note: Data on the number of citations issued was collected from the Administrative Office of the Courts for calendar year 2018. Data for a complete calendar year 2019 was not available but will be provided on the FFY 2021 ASR. Not included in the table are 67 citations issued to minors who purchase/received tobacco products.

During 2019, ALE conducted 3,823 retail outlet inspections. During these inspections, ALE issued 338 written warnings citing violations to the G.S. 14-313 youth tobacco access law.

In addition, ALE conducted 523 state compliance checks and issued 139 written warnings citing G.S. 14-313 youth access law. Follow-up inspections were conducted at the 139 outlets, and 25 outlets sold to the minor a second time. The 25 outlets were issued a citation for selling to a minor.

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:

1.	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.
е.	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
	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
	Red Flag Merchant Education Packet: North Carolina's Department of Health and Human Samilaga (DIHIS) contracted with the Covernar's Institute to excipt

- Red Flag Merchant Education Packet: North Carolina's Department of Health and Human Services (DHHS) contracted with the Governor's Institute to assist with the dissemination of 8,300 Red Flag Merchant Education packets, of which 825 were in Spanish. The packets were distributed to Local Management Entities/Managed Care Organizations (LME/MCOs), which in turn distributed them to tobacco retailers in their catchment areas, or directly to tobacco retailers. In addition, 840 state-required signs were distributed, of which 300 were in Spanish. DHHS is currently looking to conduct a brief survey with Red Flag Merchant Packet recipients to solicit their feedback on packet contents in terms of what is used/not used and suggested enhancements. The feedback will be used to improve the state's ability to effectively reduce the state's RVR through merchant education.
- LME/MCOs conducted 5,035 tobacco merchant education visits in their catchment areas. During these visits, tobacco laws were reviewed, and the outlets received the Red Flag Merchant Education packet. Currently, DHHS is working with the LME/MCOs to improve their reporting of tobacco-related activities, and the actual number of reported visits is expected to increase.
- ALE conducted 1,557 "Be A Responsible Seller/Server-BARS" trainings to 3,357 retail personnel on the laws and penalties for selling tobacco and alcohol to minors. These trainings occurred in two formats. First, during regular ALE outlet inspections the ALE Agent spent approximately 15 minutes reviewing ALE's scripted PowerPoint training that reviewed tobacco laws and the Red Flag Merchant Education packet. Second, ALE presented a more formalized 90-minute training to larger audiences which was more detailed in content.
- In August 2019, ALE went live with their online tobacco training. As of September 15, 2019, the online training had been accessed by 35 trainees.
- Incentives for merchants who are in compliance (e.g., nonenforcement compliance checks in which compliant retailers are given positive reinforcement and noncompliant retailers are warned about youth access laws)

Within 90 days after the conclusion of the FFY 2020 Synar inspections, ALE will conduct follow-up inspections on the 79 retail outlets that "intended to sell" tobacco to the youth inspector. If during this follow-up inspection the outlet sells to the youth inspector, a citation will be issued to the clerk.

Community education regarding youth access laws

LME/MCOs conducted community trainings with local agencies and other partners in their catchment areas that provided education on youth tobacco use, state/federal youth access laws, and how communities can be involved in state efforts to reduce youth access.

Media use to publicize compliance inspection results

In May, June, and September of 2019, ALE received media attention related to the state's high RVR and the potential loss of block grant funding, and the state's vaping crisis. The media coverage included print and a televised newscast.

- Community mobilization to increase support for retailer compliance with youth access laws
- The DHHS Training and Technical Assistance Center and the Governor's Institute hosted 14 regional workshops for the LME/MCOs, an increase of 11 workshops over the previous year. Among other things, the workshops were designed to increase awareness of the state's increasing RVR, explore solutions to reduce the RVR, solicit LME/MCO assistance, and improve LME/MCO reporting on tobacco related activities. LME/MCOs are required by the SSA to provide community mobilization, community and merchant education, public relations, and/or law enforcement activities for a minimum of 48 hours during each 6-month reporting period.

Other activities (*Please list.*)

For the FFY 2020 ASR inspections, DHHS changed the entity responsible for conducting the random, unannounced Synar inspections to ALE. ALE has a long history of conducting alcohol and tobacco inspections, and the change was primarily made to improve the recruitment, age testing, and training of minors; improve inspection protocols; create an opportunity to attach enforcement of G.S. 14-313 to future Synar inspections; and benefit from ALE's experience and expertise in conducting FDA inspections.

This collaborative relationship also benefited ALE in that their age testing protocols have been updated and streamlined, and the development of a new Synar inspection form includes a dual role allowing ALE to use the Synar inspection form during state tobacco inspections outside of Synar. This dual-purpose form will also enable DHHS to collect Synar-specific information from state tobacco inspections and enable additional RVR analysis in support of the Synar program.

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 2019 (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
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
Previous to the FFY 2020 ASR, DHHS used an area sampling methodology. For the FFY 2020 ASR, DHHS switch to a list frame sampling methodology. DHHS took the following steps:
• Obtained NC's FDA Tobacco Inspection Program list of tobacco outlets to use as a base list from which to build the list frame.
• Developed and implemented a coverage study pilot within a limited area to evaluate the FDA' list coverage rate before implementing a statewide coverage study.
• Based on coverage study pilot results, three additional tobacco retailer lists were obtained to improve the overall coverage rate.
• Developed and submitted a coverage study plan to SAMHSA for approval. Approval was granted on January 23, 2019.
• Conducted a statewide coverage study, which resulted in an 87.6-percent coverage rate and is included as Appendix D of the FFY 2020 ASR.
• Developed and submitted a list frame sampling methodology to SAMHSA for approval on April 30, 2019. Approval was granted on June 17, 2019, and is included as Appendix B of the FFY 2020 ASR.
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
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 1	the (weig	hted) R	VR _			
	Fill in the blanks t interval.	o calc	ulate the	<u>right li</u>	<u>mit</u> of th	e right-sid	ed 95% c	confidence
	RVR Estimate	+ plus	(1.645 (1.645	× times	Standa) ard Error)	= equals	Right Limit
	Accuracy rate							
	Completion rate							
c.	Fill out Form 1 (So of the sample design		pendix A	: Forms	s 1–5 Ter	mplates). (A	Required	regardless
d.	How were the (we (Check the one that	_		stimate	and its s	tandard er	ror obtai	ined?
	Form 2 (Optiona Form 2.)	al) (Se	e Append	lix A: Fo	orms 1–5	Templates) (Attach	completed
	Other (Please sp							-
e.	If stratification was		l, did any	y strata	in the sa	mple cont	ain only o	one outlet
e.		r?			in the sa	mple cont	ain only o	one outlet
e.	or cluster this year	r?] No st	ratificati	ion		-	·	one outlet
e.	or cluster this year ☐ Yes ☐ No ☐	r?] No st	ratificati	ion		-	·	one outlet
e. f.	or cluster this year ☐ Yes ☐ No ☐	r?] No st this si	t ratificati	i on vas deali		-	·	one outlet
	or cluster this year ☐ Yes ☐ No ☐ If Yes, explain how	r?] No st this si	t ratificati	i on vas deali		-	·	one outlet
	or cluster this year ☐ Yes ☐ No ☐ If Yes, explain how Was a cluster sam	r?] No st this si ple de	tratification was sign used	ion vas deali	t with in v	variance es	timation.	
	or cluster this year ☐ Yes ☐ No ☐ If Yes, explain how Was a cluster sam ☐ Yes ☐ No If Yes, fill out and of	r? No st this si ple de attach ag ques	tratification was sign used	ion vas deali	t with in v	variance es	timation.	
	or cluster this year ☐ Yes ☐ No ☐ If Yes, explain how ☐ Was a cluster sam ☐ Yes ☐ No If Yes, fill out and canswer the following	r? No st this si ple de attach ag ques on 7g.	sign used	ion cas deali 1? See App	t with in v	variance es Forms 1–5	timation.	
	Yes No ☐ If Yes, explain how Was a cluster sam Yes No If Yes, fill out and a answer the followin If No, go to Question	r? No st this si ple de attach ag ques on 7g.	sign used	ion cas deali 1? See App	t with in v	variance es Forms 1–5	timation.	

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

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

		Eligible sample size (number of outlets found to be eligible in the sample)	
		Final sample size (number of eligible outlets in the sample for which an inspection was completed)	
	h	. Fill out Form 4 (See Appendix A: Forms 1–5 Templates).	
8.	Did the	e 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: 2	2019
	b	. Percent coverage from the latest Sampling frame coverage study	: 87.6
	c	Was a new study conducted in this reporting period?	
		⊠Yes □ No	
		If Yes , please complete Appendix D (List Sampling Frame Coverage and submit it with the Annual Synar Report.	Study)
	d	. The calendar year of the next coverage study planned: 2022	
9.	Has th	e Synar survey inspection protocol changed from the previous year	?
	X Yes	No	
	protoco (Appen be refle	te is required to have an approved up-to-date description of the Synar of on file with CSAP. Please submit a copy of your Synar Survey Inspection C). If the inspection protocol changed from the previous year, these exted in the protocol submitted. In If Yes, describe how and when this change was communicated to	tion Protocol e changes must
	•	DHHS, developed and submitted Synar survey protocol changes to	
		approval on April 30, 2019. Approval was granted on June 17, 2019 included as Appendix B of the FFY 2020 ASR.	, and is
	b	. Provide the inspection period: From <u>07/14/19</u> to <u>9/21/19</u> MM/DD/YY MM/DD/YY	
	c	Provide the number of youth inspectors used in the current inspe	ection vear:

<u>19</u>

NOTE: If the state uses SSES, please ensure that the number reported in 9c matches

that reported in SSES Table 4, or explain any difference.

A total of 19 youth inspectors were used. One youth inspector had a date of birth anniversary and conducted inspections at two different ages.

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 2020 (Intended Use)

Public Law 42 U.S.C. 300x-26 of the Public Health Service Act and 45 C.F.R. 96.130 (e) (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**

	Synar inspection protocol Yes X 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 2020. 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.
	ALE will conduct targeted follow-up inspections on those retailers who "intended to sell" tobacco products to the youth inspector during Synar inspections. In addition, DHHS will collaborate with ALE to target additional state inspections to evaluate overall tobacco control activities such as targeted education or tobacco compliance checks using the FDA public website.
	LME/MCOs and their provider agencies will continue reporting their regional efforts in merchant education, law enforcement-related activities, and media/public relations into the statewide electronic database. This information will be further analyzed to determine if their efforts are effective, which in turn will inform DHHS's approach and directives on their future activities. For example, the SSA could direct the providers to conduct more targeted

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.)

The state does not anticipate any changes to its youth tobacco access law but will seek any opportunities to address policies that would strengthen the law. The state will continue to be

a. Limited resources for law enforcement of youth access laws

diligent in its efforts to reduce youth tobacco use and access.

DHHS continues to be concerned about the state's ability to maintain active enforcement of youth access laws. In 2014, ALE duties were realigned, which restricted how the agency conducted tobacco and alcohol compliance inspections. In 2018, The SSA was able to identify reoccurring state funds to support enforcement activities through a contract with ALE. However, these funds provide

	for a limited number of inspections and more funding would greatly impact the state's RVR.
	b. Limited resources for activities to support enforcement and compliance with youth tobacco access laws
	c. Limitations in the state youth tobacco access laws
	d. Limited public support for enforcement of youth tobacco access laws
\boxtimes	e. Limitations on completeness/accuracy of list of tobacco outlets
	North Carolina does not license its tobacco retailers and prior to the FFY 2020 ASR used an area frame for Synar sampling. For the FFY 2020 ASR, a list frame sampling methodology was implemented by combining multiple lists. While the combined list does achieve the required accuracy, coverage, and completion rates, its development does create a challenge without tobacco licensing.
	f. Limited expertise in survey methodology
	g. Laws/regulations limiting the use of minors in tobacco inspections
\boxtimes	h. Difficulties recruiting youth inspectors
	Prior to the FFY 2020 ASR, the number of youth inspectors recruited was relatively small with approximately four youth inspectors recruited for each of the last two ASRs. With few youth inspectors, the number of inspections completed by each was relatively high. DHHS felt this could create an opportunity for biases to enter the calculated RVR. DHHS's goal for the FFY 2020 ASR was to recruit 16–20 youth inspectors to not only reduce possible biases, but also reduce youth inspector travel and costs. While 19 youth inspectors were recruited, it was a challenge to achieve this number with the more stringent age testing policies implemented.
	As a result of DHHS's switch from an area frame to a list frame, additional time and resources were required to conduct a pilot coverage study and coverage study, and design the sampling methodology. In addition, this was the first year DHHS contracted with ALE to conduct the Synar inspections, which required time and resources to develop mutually agreed upon age testing procedures, inspection procedures, the inspection form, and training materials. The time required to complete these activities resulted in a shortened period of time to recruit minors before the targeted start date to begin conducting inspections.
	i. Issues regarding the balance of inspections conducted by youth inspectors age 15 and under
\boxtimes	j. Issues regarding the balance of inspections conducted by one gender of youth inspectors
	As mentioned in 3h., DHHS achieved its goal to increase the number of youth inspectors recruited. DHHS also met SAMHSA's gender balance ratio requirement

for completed inspections. However, DHHS was unable to recruit a balanced pool of youth inspectors in terms of age and gender by strata. This resulted in an imbalance of inspections completed by gender within some strata. DHHS anticipates more time to recruit youth inspectors for the FFY 2021 ASR and will require more stringent recruiting guidelines to achieve a more balanced pool of youth inspectors in each stratum.

n. Other challenges (*Please list.*) Counties with high RVRs

There was not an overall challenge to comply with the Synar regulation in terms of geography, demographics, logistics, or cultural factors. And while North Carolina's FFY 2020 RVR is a representation of the state's RVR, analysis indicates high RVRs in several counties. DHHS plans to use Synar and other data points to identify the challenges within these counties and develop strategies to reduce their RVRs.

APPENDIX A: FORMS 1–5 TEMPLATES

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

Complete Form 1 **in Excel** 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 **Excel** form, provide the state name and reporting federal fiscal year (FFY 2020). 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. These numbers will be the sum of the numbers in each row for the respective column.

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

				Sumn	norw of Sw	nor Inche	otion Dos	ults by St	ratum				
				Sullili	iary or sy	nar mspe	ction Res	uits by St	ratum		S	State:	
											I	FFY: <u>2020</u>	
(1)		(2)			(3)			(4)			(5)	
STR	ATUM		ER OF OUT IPLING FR		ELIGII	ATED NUM BLE OUTLI OPULATIO	ETS IN	NUMBER OF OUTLETS INSPECTED			NO. OF OUTLETS FOUND IN VIOLATION DURING INSPECTIONS		RING
(a) Row #	(b) Stratum Name	(a) Over-the- Counter (OTC)	(b) Vending Machines (VM)	(c) Total Outlets (2a+2b)	(a) Over-the- Counter (OTC)	(b) Vending Machines (VM)	(c) Total Outlets (3a+3b)	(a) Over-the- Counter (OTC)	(b) Vending Machines (VM)	(c) Total Outlets (4a+4b)	(a) Over-the- Counter (OTC)	(b) Vending Machines (VM)	(c) Total Outlets (5a+5b)

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 in Excel 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 **Excel** form, provide the state name and reporting federal fiscal year (FFY 2020).

- 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. These numbers should match the numbers reported in Column 4(c) of Form 1 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). Note that these numbers will be less than or equal to the numbers in Column 2.
- Column 9: Form 2 (in Excel form) will automatically calculate 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.

FORM 2 (Optional) Appropriate for stratified simple or systematic random sampling designs.

			Calc	culation of W	eighted Retai	ler Violation	Rate			
									State:	
									FFY: 2020	
	II	ı	I		ı	II		ı		II.
(1) Stratum Name	(2) N Number of Outlets in Sampling Frame	(3) n Original Sample Size	(4) n1 Number of Sample Outlets Found Eligible	(5) n2 Number of Outlets Inspected	(6) x Number of Outlets Found in Violation	(7) p=x/n2 Stratum Retailer Violation Rate	(8) N'=N(n1/n) Estimated Number of Eligible Outlets in Population	(9) w=N'/Total Column 8 Relative Stratum Weight	(10) pw Stratum Contribution to State Weighted RVR	(11) s.e. Standard Error of Stratum RVR
Total										

N - number of outlets in sampling frame

n - original sample size (number of outlets in the original sample)

n1 - number of sample outlets that were found to be eligible

n2 - number of eligible outlets that were inspected

x - number of inspected outlets that were found in violation

p - stratum retailer violation rate (p=x/n2)

N' - estimated number of eligible outlets in population (N'=N*n1/n)

w - relative stratum weight (w=N'/Total Column 8)

pw - stratum contribution to the weighted RVR

s.e. - standard error of the stratum RVR

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 in Excel 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 **Excel** form, provide the state name and reporting federal fiscal year (FFY 2020).

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

Column 1: Sequentially number each row.

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.

Report the number of primary sampling units (PSUs) (i.e., first-stage clusters) created for Column 3: each stratum.

Column 4: Report the number of PSUs selected in the original sample for each stratum.

Report the number of PSUs in the final sample for each stratum. Column 5:

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

	Summary of Clusters	\$	State:	
			FFY: 2020	
(1) Row#	(2) Stratum Name	(3) Number of PSUs Created	(4) Number of PSUs Selected	(5) Number of PSUs in the Final Sample
	Total			

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

Complete Form 4 **in Excel** 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 **Excel** form, provide the state name and reporting federal fiscal year (FFY 2020).

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."

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					
	State:				
FFY: 2020					
(1) INELIGIBLE		(2) ELIGIBLE			
Reason for Ineligibility	(a) Counts	Reason for Noncompletion	(a) Counts		
Out of business		In operation but closed at time of visit			
Does not sell tobacco products		Unsafe to access			
Inaccessible by youth		Presence of police			
Private club or private residence		Youth inspector knows salesperson			
Temporary closure		Moved to new location			
Unlocatable		Drive-thru only/youth inspector has no driver's license			
Wholesale only/Carton sale only		Tobacco out of stock			
Vending machine broken		Ran out of time			
Duplicate		Other noncompletion reason(s) (Describe.)			
Other ineligibility reason(s) (Describe.)					
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 **in Excel** 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 **Excel** form, provide the state name and reporting federal fiscal year (FFY 2020).

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 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 Charac	teristics
		State:
		FFY: 2020
	(1) Attempted Buys	(2) Successful Buys
Male		
15 years		
16 years		
17 years		
18 years		
19 years		
20 years		
Male Subtotal		
Female		
15 years		
16 years		
17 years		
18 years		
19 years		
20 years		
Female Subtotal		
Other		
Total		

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 2019.

APPENDIX B: SYNAR SURVEY SAMPLING METHODOLOGY

State:	North Carolina
FFY:	2020

 What type of 	f sampling	frame is	used?
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\boxtimes	List frame (Go to Question 2.)
	Area frame (Go to Question 3.)
П	List-assisted area frame (Go to Ouestion 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 (method), 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.

1 – Statewide commercial business list
 2 – Local commercial business list
 4 – Statewide retail license/permit list
 5 – Statewide liquor license/permit list

3 – Statewide tobacco license/permit list 6 – Other

Name of Frame Source	Type of Source	Description	Updating Method and Cycle
FDA List Frame (Tobacco Inspection Management System (TIMS)	6	Frame file used by FDA to conduct tobacco compliance checks	We will obtain an updated file each year from the FDA, in advance of the annual NC Synar study, to use as the basis for the NC Synar frame. NC will provide updates, based on the annual Synar frame and field study activities, back to the FDA for their use in updating the FDA frame file.
NC Weights and Measures Service Station List	4	List of NC service stations dispensing gasoline. List is maintained by the State.	An updated version of this file will be obtained each year as part of the frame maintenance process. New and revised service station information will be merged onto the frame file.
Family Dollar and Dollar General stores list	1	Commercial list of all Family General and Dollar General stores in North Carolina	This list will be updated every year as part of the frame maintenance process. New and revised store information will be merged onto the frame file.

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.
	 State has a contract with the FDA and is actively enforcing the vending machine requirements of the Family Smoking Prevention and Tobacco Control Act.
	Other (Please describe.)
	If Yes, please indicate how likely it is that vending machines will be sampled.
	☐ Vending machines are sampled separately to ensure vending machines are included in the sample
	☑ Vending machines are sampled together with over the counter outlets, so it is
	possible that no vending machines were sampled, however they are included in the sampling frame and have a non-zero probability of selection
	Other reasons (<i>Please describe</i> .)
5.	Which category below best describes the sample design? (Check only 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.

Strata will be formed by using the eight districts of the Alcohol Law Enforcement (ALE) branch of the North Carolina State Bureau of Investigation, each formed by an aggregation of several counties. ALE is the State law enforcement agency responsible for youth tobacco enforcement and will be conducting the fieldwork for the NC Synar studies. These districts are shown in a map below:





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.)

Clusters will be individual counties, each randomly selected from within the ALE districts.

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.

At the first stage of sampling, two counties will be randomly selected, with equal probability, from each of the ALE Divisions.

At the second stage of sampling, tobacco outlets from the frame will be randomly selected, with equal probability within the selected county, for each of the counties selected at the first stage.

The allocation of the total sample size to the ALE Districts will be made proportional to the number of outlets on the frame within each district. Within each district, the allocation of sample size to its two selected counties (in stage one) will be made using the relative proportion of outlets within each county.

For instance (numbers are for demonstration purposes only), for District 1 with sampled counties A and B, if County A has 100 outlets on the frame while County B has 150 outlets, and the sample size proportionately allocated to District 1 is 200 outlets, then County A sample size is computed as:

Sample Size County
$$A = 200 \times \frac{100}{(100 + 150)} = 80$$
 Tobacco Outlets

The calculation for County B is given by:

Sample Size County
$$B = 200 \times \frac{150}{100 + 150} = 120$$
 Tobacco Outlets

Each of the 16 counties selected from the 8 ALE Districts will be sampled in this manner.

When the full Synar sample has been drawn, each outlet will be randomly allocated to be inspected either as a cigarette inspection, or as a smokeless tobacco inspection. Within each county's sample, 75% of the outlets will be allocated as cigarette inspections, while the remaining 25% will be allocated as smokeless tobacco inspections. See Appendix C for further details about implementation.

- 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:

Source information is provided for each item used to calculate sample size.

Inputs for Effective Sample Size:

RVR: **20.8%** Percentage indicated is from FY2019 SSES. For years beyond FY2020, State will use a conservative 20% each year to compute total sample size.

Frame Size: **10,949** Number indicated is from FY2019 SSES. Each year's sample size calculations will use actual frame size at time of sampling.

Input for Target Sample Size:

Design Effect: **1.0** Value indicated is a conservative estimate of the design effect, to be kept constant year to year.

Inputs for Original Sample Size:

Safety Margin: 25% This value is a conservative safety margin that will provide protection from deviations in the sample size inputs. This value will be kept constant year to year.

Accuracy (Eligibility) Rate: **80%** This percentage is a conservative estimate of frame accuracy, is the lower threshold of acceptable SAMHSA accuracy, and will be kept constant year to year.

Completion Rate: 95% This percentage is a conservative estimate of the completion rate and will be kept constant year to year.

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:

To be determined prior to sampling, after frame maintenance completed.

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: SYNAR SURVEY INSPECTION PROTOCOL SUMMARY

State: North Carolina

FFY: 2020

1.	How do	es the state Synar survey protocol address the following?
	a.	Consummated buy attempts?
		☐ Required ☐ Permitted under specified circumstances (Describe:)
		☐ 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: The ALE Agent enters the outlet first to facilitate their assessment of the outlet's safety. If the ALE Agent detects an unsafe condition before or after entering the outlet, they return to the vehicle before the Youth Inspector leaves the vehicle. Once inside the outlet, the ALE Agent will position themselves to see and hear the transaction. However, there may be occasions when only one mode of observation is possible. The ALE Agent's position should also facilitate their ability to intercede if a problem arises involving the Youth Inspector.
		After the Agent enters the outlet, the Youth Inspector waits 15-20 seconds before exiting the vehicle. This allows the ALE Agent inside the outlet to assess its safety After 15-20 seconds have elapsed, the Youth Inspector leaves the vehicle at the direction of the second ALE Agent who remains in the vehicle. It is the responsibility of the ALE Agent that remains in the vehicle to monitor (direct line of sight) the Youth Inspector's safety during their approach to the outlet.
		On rare occasions it is permissible for the Youth Inspector to enter the outlet without the presence of the ALE Agent. These occasions usually occur when the outlet is very small, and it is difficult for the ALE Agent and Youth Inspector to enter without appearing to be together.)
		☐ 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): North Carolina Alcohol Law Enforcement (ALE)
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.
	Age-restricted tobacco products eligible for purchase are cigarettes and smokeless
	tobacco products only. The priority order of the tobacco product purchase attempts
	tobacco products only. The priority order of the tobacco product purchase attempts is: First, attempt to purchase cigarette or smokeless tobacco products from a self-
	tobacco products only. The priority order of the tobacco product purchase attempts is: First, attempt to purchase cigarette or smokeless tobacco products from a self-service display or vending machine. Second, attempt to purchase cigarette or
	tobacco products only. The priority order of the tobacco product purchase attempts is: First, attempt to purchase cigarette or smokeless tobacco products from a self-
	tobacco products only. The priority order of the tobacco product purchase attempts is: First, attempt to purchase cigarette or smokeless tobacco products from a self-service display or vending machine. Second, attempt to purchase cigarette or smokeless tobacco product from over-the-counter.
	tobacco products only. The priority order of the tobacco product purchase attempts is: First, attempt to purchase cigarette or smokeless tobacco products from a self-service display or vending machine. Second, attempt to purchase cigarette or smokeless tobacco product from over-the-counter. The preferred ratio of tobacco products purchase attempts is: The Youth Inspector
	tobacco products only. The priority order of the tobacco product purchase attempts is: First, attempt to purchase cigarette or smokeless tobacco products from a self-service display or vending machine. Second, attempt to purchase cigarette or smokeless tobacco product from over-the-counter. The preferred ratio of tobacco products purchase attempts is: The Youth Inspector will attempt to purchase cigarettes on 75% of the purchase attempts. The Youth
	tobacco products only. The priority order of the tobacco product purchase attempts is: First, attempt to purchase cigarette or smokeless tobacco products from a self-service display or vending machine. Second, attempt to purchase cigarette or smokeless tobacco product from over-the-counter. The preferred ratio of tobacco products purchase attempts is: The Youth Inspector
	tobacco products only. The priority order of the tobacco product purchase attempts is: First, attempt to purchase cigarette or smokeless tobacco products from a self-service display or vending machine. Second, attempt to purchase cigarette or smokeless tobacco product from over-the-counter. The preferred ratio of tobacco products purchase attempts is: The Youth Inspector will attempt to purchase cigarettes on 75% of the purchase attempts. The Youth Inspector will attempt to purchase smokeless tobacco on 25% of the purchase
	tobacco products only. The priority order of the tobacco product purchase attempts is: First, attempt to purchase cigarette or smokeless tobacco products from a self-service display or vending machine. Second, attempt to purchase cigarette or smokeless tobacco product from over-the-counter. The preferred ratio of tobacco products purchase attempts is: The Youth Inspector will attempt to purchase cigarettes on 75% of the purchase attempts. The Youth Inspector will attempt to purchase smokeless tobacco on 25% of the purchase attempts. Inspection forms will be pre-printed with the county, outlet name and

a.

b.

(If **Yes**, please describe.)

The brands of cigarettes or smokeless tobacco products requested is determined by: DHHS provides a list of eligible products by category (cigarettes and smokeless tobacco) to ALE. The inspection team chooses the product(s) to be requested from the DHHS list of eligible products at the beginning of the inspection shift and the Youth Inspector requests the selected product(s) for the remainder of the day.

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

Adult supervisors are ALE Agents and are selected to participate based on the geographic location of the randomly selected outlets and ALE Districts. ALE Agents receive compliance check training for alcohol and tobacco through their agency. In addition, ALE inspection procedures have been amended to include Synar specific inspection protocols.

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

Youth inspectors are generally recruited by the ALE Agents within their network of contacts and can include Youth Inspectors from other programs such as FDA inspections. If ALE Agents have trouble recruiting in a specific area, ALE will contact DHHS to assist in recruitment.

Once recruited, the Youth Inspector candidates undergo age testing to ensure their perceived age meets DHHS guidelines. If the Youth Inspector candidate meets the age testing requirements they are then hired by ALE.

ALE agents provide Synar specific training to the youth inspectors prior to conducting any Synar inspections. The instructions include specific information on the role and responsibilities of the Youth Inspector, followed by role-play exercises covering various scenarios to prepare the Youth Inspector for the types of questions they should expect from retail employees and their correct responses.

6.	Are there specific legal or procedural requirements instituted by the state to address
	the issue of youth inspectors' immunity when conducting inspections?

e specific legal or procedural requirements instituted by the state to address of youth inspectors' immunity when conducting inspections?
Legal
⊠ Yes □ No
(If Yes , please describe.)
NCGS 14-313 makes it illegal for a person less than 18 years of age to purchase, acquire or receive tobacco products or cigarette wrapping papers. The two exceptions are if the minor is enlisted by a police or sheriff's department to test compliance or if the minor is working with the NC Department of Health and Human Services to conduct annual, random, unannounced inspections. In both situations prior parental consent is required.
Procedural
☐ Yes ⊠ No

(If **Yes**, please describe.)

7.		re specific legal or procedural requirements instituted by the state to address e of the safety of youth inspectors during all aspects of the Synar inspection?
	a.	Legal
		☐ Yes ⊠ No
		(If Yes , please describe.)
	b.	Procedural

When meeting the Youth Inspector to start the inspection shift, the ALE Agent will direct the Youth Inspector to inform their parent(s) they are with the inspection team. When the inspection shift ends, the inspection team will return the Youth Inspector to a location pre-approved by their parents and direct the Youth Inspector to contact their parent(s) to inform them the inspection shift has ended, and they are no longer with the inspection team. Meeting and dropping off the Youth Inspectors must include the presence of two ALE Agents.

Prior to arriving at a randomly selected outlet, the inspection team will discuss an inspection plan for the outlet. The discussion will include: 1) who will enter the outlet and in what order, 2) what type of tobacco product is to be attempted for purchase, 3) from where the tobacco product purchase attempt is made, e.g., self-service display, over-the-counter or vending machine, and 4) a review of safety measures specific to the outlet.

Upon arriving at each outlet, the driver will attempt to park in a location that is not visible to the clerk. The inspection team should also scan for exterior CCTV cameras which may also alert the clerk.

The safety of the inspection team is DHHS's number one priority and any outlet randomly selected for inspection can be omitted when there is a safety concern. Any member of the inspection team can deem the location unsafe. A signal for aborting the location due to safety concerns should be established prior to any member of the team entering the location. It is always preferred the Youth Inspector is directly supervised and the ALE Agents maintain a direct line of sight on the Youth Inspector during the entire purchase attempt including: 1) their departure from the vehicle until entering the outlet; 2) while in the outlet; and 3) departure from the outlet and returning to the vehicle. The preferred order to enter the outlet is:

The ALE Agent enters the outlet first to facilitate their assessment of the outlet's safety. If the ALE Agent detects an unsafe condition before or after entering the outlet, they return to the vehicle before the Youth Inspector leaves the vehicle. Once inside the outlet, the ALE Agent will position themselves to see and hear the

a.

b.

(If **Yes**, please describe.)

transaction. However, there may be occasions when only one mode of observation is possible. The ALE Agent's position should also facilitate their ability to intercede if a problem arises involving the Youth Inspector.

After the Agent enters the outlet, the Youth Inspector waits 15-20 seconds before exiting the vehicle. This allows the ALE Agent inside the outlet to assess its safety. After 15-20 seconds have elapsed, the Youth Inspector leaves the vehicle at the direction of the second ALE Agent who remains in the vehicle. It is the responsibility of the ALE Agent that remains in the vehicle to monitor (direct line of sight) the Youth Inspector's safety during their approach to the outlet.

On rare occasions it is permissible for the Youth Inspector to enter the outlet without the presence of the ALE Agent. These occasions usually occur when the outlet is very small, and it is difficult for the ALE Agent and Youth Inspector to enter without appearing to be together.

Upon the Youth Inspector's departure from the outlet, the ALE agent will also leave the outlet and return to the vehicle but doing so discretely as to not bring undue attention to the inspection team. This may require a slight delay before the ALE Agent leaves after the Youth Inspector. When all members of the inspection team return to the vehicle, the team will drive to a safe location to complete the inspection form and debrief the inspection.

8. Are there any other legal or procedural requirements the state has regarding how inspections are to be conducted (e.g., age of youth inspector, time of inspections, training that must occur)?

Legal	
☐ Yes ⊠ No	
(If Yes , please describe.)	
Procedural	
⊠ Yes □ No	

All youth inspectors shall participate in age verification testing before being allowed to participate. Youth Inspectors participating in Synar activities should be age tested every 3-6 months.

A total of twelve (12) State Employees will be used to conduct age testing for each underage person. Ten ALE Supervisors' opinions will be combined with two opinions from DHHS/DMH representatives. The opinions of the underage person's age shall be recorded on the form approved and prescribed by DHHS/DMH and Division Headquarters. DHHS/DMH and SBI/ALE should make every effort to secure opinions from varied participants that include differences in age, sex, race, and ethnicity. When twelve (12) opinions have been secured and recorded on the testing form, DHHS/DMH and SBI/ALE shall average the results and record the average in the appropriate box on the form.

If the age verification testing average age of the underage person is not within the appropriate age parameters, the underage person cannot be utilized in investigations of alcohol sales or tobacco product distribution to underage persons. If the age verification testing average age of the underage person is within the appropriate age parameters, the underage person shall be processed for participation in investigations of alcohol sales or tobacco product distribution to underage persons

Synar Inspections: No person older than 17 years 10 months of age shall be employed as underage persons.

Compliance employees shall not be used in these operations between the hours of 11 p.m. and 5 a.m. if the underage person has school the next day.

APPENDIX D: LIST SAMPLING FRAME COVERAGE STUDY

(LIST FRAME ONLY)

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b. Describe the sampling methods.

If No, respond to Question 9.

canvassed, then go to Question 10.

A simple random sample of 14 census tracts was initially selected based on the results of a small pilot study. An additional selection of 17 census tracts was made in case the results of the pilot study were not representative of an average North Carolina census tract, or insufficient numbers of tobacco outlets were found in the initial selection of census tracts. All 31 selected census tracts were used for this study and were canvassed.

	c.	Provide a full description of the strata that were created.
	d.	Provide a full description of how clusters were formed.
5.	Were bo	orders of the selected areas clearly identified at the time of canvassing?
	Yes	□ No
6.	Were al	l sampled areas visited by canvassing teams?
	∑ Yes	(Go to Question 7.) \[\bigcap \bigcap \bigcap \bigcap (Respond to Parts a and b.) \]
	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 fie	eld observers provided with a detailed map of the canvassing areas?
	Yes	□ No
	If No , de	escribe the canvassing instructions given to the field observers.
8.	Were fie	eld observers instructed to find all outlets in the assigned area?
	Yes	\square No

Once the sample of census tracts was drawn, the team developed maps to be used for the coverage study field work. To ensure that the maps were at a large enough scale to be readable by the canvassing teams, the census tracts was broken up into their constituent census block groups for which maps were created. Driving directions were created for each census block group map, and the map was marked accordingly with these directions. Accommodations were made for the driving directions overlap between adjoining census block groups within the census tract, to ensure complete coverage. Canvassing was

If Yes, describe any instructions given to the field observers to ensure the entire area was

conducted only within the interior of the census tract, as defined by its boundaries. Within the interior of the census tract, canvassing was conducted on both sides of the street, while on the boundaries, canvassing was only conducted on the side of the street that was within the census tract boundary. Observers ticked off streets on map to indicate they had been canvassed, reviewed maps to ensure all streets had been canvassed, and forwarded photos of maps with canvassing results to NC DHHS.

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.
	е.	Please describe the canvassing instructions given to the field observers, including predetermined routes.

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

Each canvassing team consisted of one driver and one navigator/observer. The navigator guided the driver using driving instructions marked on the maps and was looking for potential outlets to investigate. When a potential tobacco outlet was spotted, the team stopped and confirmed eligibility by entering the establishment to observe that it both sold tobacco products that are included in the North Carolina Synar study, and was accessible to minors.

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).

When a tobacco outlet was found, its information was added to the fieldwork coverage study form maintained by the canvassing team. This information included census tract ID, name of the business, address of the business, and other notes relevant to the outlet. The team also took a photograph using a cell phone to be used if needed for matching to the frame.

The data from the forms was input into a spreadsheet format, which was used to compare to the list frame. All tobacco outlets found in the field that clearly matched outlets on the list frame, were indicated on the spreadsheet as matches. Those tobacco outlets found in the field that did not match an outlet on the list frame were initially indicated as missing and investigated further. Some reasons for initially unmatched outlets, where a match on the list frame may ultimately be found, included a new owner changing the name of the outlet, a recording error in either list frame or the fieldwork form, and streets known by several names. All available information, including notes on the fieldwork form, and consulting with

the canvassing team, were used to determine if unmatched outlets could be matched. When this review was completed, each outlet found was coded as either matched or missing.

The definition of a match: address and name could be tied to list file, and if the name did not match, the address matched, and we could verify updated name using the photos provided by canvassers along with a web search.

Mismatched meant that we did not have an outlet on the list at the indicated address found by the canvassers and were unable to reconcile using the photo or with web searches.

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

A simple random sample of census tracts was drawn so no weights are required.