

**Questions for the Food and Drug Administration (FDA) Tobacco Retail
Inspections
(Due Date November 30, 2020)**

Issuing Agency: NC Department of Health and Human Services (NC DHHS), Division of Mental Health, Developmental Disabilities, and Substance Abuse Services

Attn: Christopher Drew

1.2 Background

- A. Please confirm the contractor is expected to conduct inspections using older Underage Purchasers (UP) aged 18 to 20. If yes, does this create additional processes related to ALE's involvement outside of ALE processes when using UPs aged 16-17?

Yes. The expectation is for the contractor to recruit and hire underage purchasers between the ages of 18-20 years of age. The contractor will also have to coordinate schedules with ALE to chaperone inspections with 16-17 year olds until the state of NC adopts a T21 law.

3.0 Award Information

- A. The RFP states, "Proposed budgets cannot exceed each year's award. Applicants must strictly adhere to the operational budget, which summarizes all applicable costs related to meeting annual FDA contract deliverables and comply with the terms outlined in this RFA."

It is understood that the operational budget cannot exceed the annual award. However, can individual line items be amended? **Yes, with state and FDA approval.**

- B. The contractor must commit up to 5 FTEs. Are the full-time, part-time, and state-contracted NC FDA program staff currently employed by the state? Are they required to transition to the new contractor? Is the contractor permitted to staff other personnel or only those identified by the state? **The state is not allowed to determine the contractor's personnel. However, the state does have personnel paid out of the current FDA contract through another vendor. The contractor must present the best proposal deemed necessary to ensure a smooth transition.**

3.1 Source of Funds and Pass Through Requirements

- A. Please confirm at the top of page four "\$67,906" is a possible error. **No. Per page four on the FDA RFA at <https://files.nc.gov/ncdhhs/FDA-RFA.docx.pdf> is as follows (which is not an error). "Anticipated Award Amount: \$676,906 Year 1(Option Yr. 3); \$693,882 Year 2(Option Yr. 4)"**

5.0 Scope of Work

- A. Are the 3,000 UB inspections Contractor Directed, FDA Directed or a combination of both? If a combination, do you have an approximate ratio of each? **No. There are 3,000 contracted directed and 1,000 A&L inspections which total 4,000 annual inspections.**
- B. Is ALE only required to participate in the inspections that use 16- and 17-year-old underage purchasers? **Yes.** Is ALE required to participate during A&L inspections? **No.**

- C. Will allowances be made to the required number of inspections if COVID-19 restrictions are in place? **COVID-19 restrictions are directed and guided by the FDA.**
- D. Who is responsible for providing personal protective equipment related to COVID-19? **The Contractor will be responsible for providing PPE equipment; however, it is an allowable cost reimbursement from the state and FDA.**
- E. Is the expectation that state-contracted NC FDA program staff become contractor employees? **The state is not allowed to direct Contractor(s) their hiring processes. However, the state expects the Contractor to ensure personnel(s) is qualified and approved by the State and FDA guidelines to conduct business as directed by the contract.** If yes, does their employment become a simple pass through for the contractor?
- F. Can the 3 regional trainings be conducted virtually? **Yes.**
- G. Please confirm where evidence is to be stored, with the contractor or with DMH/DD/SAS. **Evidence is to be stored and responsible by the Contractor. The contractor may also get approval from the FDA for storage fee quotes.**

5.1 Programmatic Requirement and Priorities

- A. For UB inspections, does the inspection team (Inspector, Law Enforcement Officer (LEO) and UP) travel together in a single vehicle? If not, does the contractor provide travel for the LEO in a separate vehicle? **Yes. Currently the Inspector and the underage purchaser travel separately from the LEO. ALE travel is covered in their MOU. If local LEO is utilized, the contractor may have to cover their travel, however, currently local LEO doesn't submit any travel expenses to the state.**
- B. Are the Program Coordinator and Back-Up Program Coordinator state employees or employed by the contractor? **Program Coordinator and Back-up Program Coordinator are employed by the Contractor. Currently, one full-time state FDA inspector is employed by the state that covers the Western region.**

5.2 Contractor Responsibilities

- A. Is mileage reimbursement acceptable in addition to leasing vehicles? **Leasing vehicles is not an allowable expense from the FDA.**
- B. Are the "FDA Inspector trainings meeting space" the same as the 3 regional trainings? **Yes. The regional trainings are suggested (not a requirement) and no other meetings are usually scheduled. It is usually a central meeting in Raleigh once or twice a year. It used to be regional but typically, they have central meeting so that the main FTE does not occur overnight travel. It is an option to have region trainings.**
- C. How many individuals are expected to attend the FDA PC Conference? **One is required by the FDA which is the Program Coordinator. However, the FDA also allows the back-up PC to attend the conference.**
- D. The RFP states, "Hire staff up to five FTEs and a pool of part-time underage purchasers and possibly local law enforcement (LEOs) as needed." Under what conditions are the LEOs hired "as needed?" **Correct. Currently, ALE is utilized for UB inspections with 16 and 17-year-old.**

5.3 Performance Standards and Expectations

- A. Who incurs the cost of the federal background checks? **The contractor incurs the cost. However, it is an allowable and reimbursable expense from the state and FDA.**
- B. What is the process for LEOs being “cleared”? **FDA does have to clear LEOs. However, the process is much shorter than the clearance process for the commissioned inspectors. LEOs must provide a letter from their agency which needs to include the date of their last background check.**

5.4 Reporting Requirements

- A. Is the annual DMH site visit on-site or virtual? **It can be a virtual meeting.**
- B. Can additional information be provided on the type of reporting required? For example, can the templates cited in this section be provided for review? **Yes.**

7.0 Terms of Contract, Option to Extend

- A. This section indicates there are two possible option years, however in section 8.0 Budget the number of option years cited is one. Please confirm how many option years are available and if budgets are to be submitted for option years. **Yes. It is two option years. Please submit a budget for two option years.**

8.0 Budget

- A. Related to procurement cards for lodging and if current inspectors are expected to transfer to the contractor, where are current inspectors located? **Current staff are in the central and eastern part of the state. However, part-time staff are located across the state.** If lodging is required if more than two hours from home, who provides the pre-approval, the contractor or DHHS? **Contractor approves travel and reimburse employees.**
- B. What is the allowable indirect cost rate? **No more than 10-20% of the contract.**