Menthol-Flavored Tobacco Product Policy Evaluation

New [OMB No. 0920-xxxx] [OMB expiration date]

Supporting Statement A

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ATTACHMENTS

JUSTIFICATION SUMMARY

Goal of the project: The Menthol-Flavored Tobacco Product Policy Evaluation will evaluate the impact of local policies restricting the sale of menthol-flavored tobacco products (hereafter referred to as menthol tobacco products). This evaluation will compare cities with policies restricting the sale of menthol tobacco products and cities with similar demographic characteristics without these policies. Outcomes of interest include commercial tobacco product use and related behaviors, perceived access to menthol tobacco products, and menthol tobacco product-related beliefs and perceptions. This information collection focuses on groups who use commercial menthol tobacco products at higher rates including people who identify as lesbian, gay, bisexual, transgender, queer, or another sexual or gender minority (LGBTQ+) and racial and ethnic minority groups (persons identifying as American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, Hispanic or Latino, or multiracial).

Intended use of the resulting data: The information collected from this evaluation will help in understanding the impact of policies that restrict the sale of menthol tobacco products both on the general population and populations experiencing tobacco-related health disparities. The findings of this information collection may be used to guide public health initiatives, programs, and policies aimed at preventing the availability, initiation of use, and consumption of menthol tobacco products.

Methods to be used to collect: This is a mixed-methods cross-sectional evaluation that will use two data collection methods: (1) a web panel survey administered to residents of selected jurisdictions with and without menthol tobacco sales restriction policies, and (2) a series of web-based community focus groups with persons living in cities with menthol tobacco sales restriction policies.

The subpopulation to be studied: This information collection examines tobacco-related knowledge, attitudes, and behaviors among adults (aged ≥18 years) who have ever regularly used or currently use tobacco and who reside in selected cities with and without menthol tobacco sales restriction policies. This collection will also focus on two

subpopulations that use menthol tobacco products at higher rates than the general population: (1) racial and ethnic minority groups; and (2) the LGBTQ+ population. CDC optimized site selection in order to have a large enough sample of each group to understand the impacts of sales restriction policies on these populations.

How the data will be analyzed: CDC will compare survey responses from residents of cities with menthol tobacco product sales restriction policies to survey responses from residents of comparable cities without these policies. We will assess outcomes among the general population, racial and ethnic minority groups, and among persons who identify as LGBTQ+. CDC will use bivariate analyses and multivariate logistic regression to assess the associations between tobacco-related behavior, knowledge, and attitudes and the presence of a menthol tobacco product sales restriction policy. CDC will also conduct thematic analysis coding with qualitative data from the community focus groups. We will analyze these data to examine how menthol sales restriction policies impact tobacco use knowledge, attitudes, and behaviors.

A. JUSTIFICATION

A1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) Office on Smoking and Health (OSH) seeks OMB approval for a new Information Collection Request for a three-year period. CDC is authorized to collect the information under Section 301 of the Public Health Service Act [42 USC 241] found in attachment 1. In 2009, the U.S. Food and Drug Administration (FDA) prohibited the sale of flavored cigarettes nationwide. However, this restriction did not apply to non-cigarette tobacco products such as cigars, e-cigarettes, or hookah, and it did not include menthol tobacco products. In April 2022, the FDA proposed new rules to expand the 2009 restriction on flavored cigarettes.[1] The proposed regulations would prohibit the sale of menthol-flavored cigarettes and all flavors in cigars, including menthol. However, it may take several years for this policy to take effect, if enacted. To date, some state and local governments in the U.S. have passed restrictions on the sale of flavored tobacco products; some of these policies explicitly ban the sale of menthol tobacco products. According to a 2023 report published by the Truth Initiative, 395 localities and three Native American tribes have implemented

restrictions on the sale of flavored tobacco products. Of these, 124 localities had comprehensive policies restricting access to menthol tobacco products.[2] As of early 2023, six states (California, Maine, Massachusetts, New Jersey, New York, and Rhode Island) had implemented some form of a sales restriction policy that included menthol tobacco products.

CDC seeks to assess how policies restricting the sale of menthol tobacco products affect tobacco-related perceptions, knowledge, and behavior among the general population, people from different racial and ethnic groups, and persons who identify as LGBTQ+. CDC routinely monitors the impact of local and state tobacco control policies. This evaluation will contribute to the existing evidence base on tobacco-related disparities, public sentiment regarding tobacco product sales restrictions, and will assess the effects of the policies, including product switching behavior and changes in tobacco purchasing patterns. This evaluation examines the impact of policies restricting the sale of menthol tobacco products to inform tobacco-related public health practices. CDC has no relevant cooperative agreement or grant numbers to cite for this work.

A2. Purpose and Use of the Information Collection

The proposed information collection aims to evaluate the impact of policies that restrict the sale of menthol tobacco products. It will measure outcomes such as the use of menthol tobacco products, quitting behavior, and product switching behavior, as well as knowledge, perceptions, and beliefs about the harms of menthol tobacco use. The information collection will also assess knowledge and perceptions of implemented policies. To conduct this information collection, OSH will collect web panel survey data from 5,366 individuals who are 18 years of age or older, that currently use, or have ever regularly used tobacco, and reside in selected sites with sales restriction policies (Boston, MA; Columbus, OH; Minneapolis and St. Paul, MN; Oakland, CA; Portland, OR; San Diego, CA, and Washington, DC) or in selected comparison sites (Atlanta, GA; Baltimore, MD; Cleveland, OH; Detroit, MI; Milwaukee, WI).[1] Additionally, OSH will collect focus group data from 75 individuals who are 18 years of age or older, who currently use tobacco or who have recently quit and reside in the selected sites with implemented sales restriction policies. Participants will be recruited online via Qualtrics, a market research services vendor, using the recruitment language found in attachments 2a and 2b.

[1] The state of Ohio recently passed a preemption law overruling Columbus's menthol tobacco product sales restriction policy. As a result, Columbus may be replaced in the final evaluation. For any other city with a newer menthol tobacco product sales restriction policy, if court litigation results in removal of the policy prior to implementation of the evaluation protocol, CDC will replace the city with a comparable city that has a menthol tobacco product sales restriction policy.

CDC will gather cross-sectional data at least six months after the implementation of the menthol tobacco product sales restriction policy in the selected sites with a policy in place. These sites will all have a sales restriction implemented by January 2024. Before participating in a focus group or the web panel survey, all participants are required to sign a consent form (attachments 3a and 3b) and complete a screening questionnaire (attachments 4a and 4b). The data collection instruments, including the web-based survey questionnaire and focus group moderator guide, can be found in attachments 5a and 5b. Screenshots of web-based data collection pages are shown in attachment 6.

The data collected will include use of any tobacco products, the types of tobacco products used, as well as past and current frequency of use. The proposed information collection will also examine quitting behaviors, such as the length of quit attempts and intention to quit. Other indicators that will be examined include product-switching behavior (e.g., from menthol to non-menthol tobacco products), perceptions, beliefs about the harms of menthol and other flavored tobacco products, and awareness of the local sales restriction policy (only in sites with policies in place).

This data collection is needed because web panel and focus group data at the local level, across multiple jurisdictions, has not been studied to date, nor does the information to be collected currently exist in any existing national, publicly available data source. The fact that this information collection focuses on racial and ethnic minority and LGBTQ+ populations who use menthol tobacco at a higher prevalence than the general population makes it unique compared to other menthol tobacco sales restriction policy evaluations. CDC acknowledges that there is sufficient evidence regarding the relationship between menthol tobacco product use and increased youth and young adult initiation, increased progression to daily use of tobacco products, and reduced cessation success. Tobacco control policies that restrict the sale of flavored tobacco products, including menthol tobacco products, show a reduction in tobacco use initiation among youth and reduce overall tobacco product use.[3] Policies that prohibit the sale of menthol cigarettes also have increased quit attempts and quit successes. CDC routinely monitors the impact of local and state tobacco control policies. Results from this information collection will add to the current evidence base by assessing the impact of local policies that restrict the sale of menthol tobacco products on tobacco-related behaviors, perceptions, and knowledge among adults from the general population and among groups that experience tobacco-related disparities. This proposed information collection is unique because it focuses on disparately affected populations, and the findings from this data may inform programs and policies that lead to improved health equity.

CDC can only complete this type of information collection by administering surveys and conducting focus groups within the selected localities and among the focus populations. Thus, this evaluation must employ primary data collection as outlined.

A3. Use of Improved Information Technology and Burden Reduction

Data collection activities include recruiting and screening eligible participants, obtaining informed consent among participants, administering surveys, and conducting focus groups. CDC will collect all primary data online, allowing participants to complete the information collection activities at a convenient location and time. In addition, online data collection will reduce the costs associated with data collection.

Deloitte Consulting LLP, CDC's contractor for this evaluation, has established a sub-contract with Qualtrics, a market research services firm. Qualtrics will recruit participants for the information collection's survey and focus group through Qualtrics's online web panel partnerships. All participants will use technology to access the web panel survey and virtual focus groups. Qualtrics will administer surveys through their survey platform and will use skip logic so that respondents only see applicable questions. Skip logic will save the respondent time in completing the survey. The Qualtrics platform is also 508 compliant to meet accessibility standards and allows those who use third-party screen readers to participate. Participants will be able to access the survey with either a personal computer, tablet, or mobile phone.

CDC will use Zoom, an online communications platform, to conduct web-based focus groups, saving participants the burden of travel time and cost. Trained evaluators from Deloitte will facilitate the focus group discussions. Deloitte will record audio and video for the focus groups, limiting the burden on the interviewer and the need to take handwritten notes. The recording will allow Deloitte to capture participant responses accurately, enabling the discussion moderator to focus on building and maintaining a positive rapport with participants.

A4. Efforts to Identify Duplication and Use of Similar Information

This ICR will not involve formal collaborations with other federal agencies or academic institutions/NGOs. However, CDC met with representatives from the FDA on two occasions to discuss this information collection and the FDA's ongoing tobacco evaluation work. The goal of consulting with the FDA was to prevent

duplicative efforts and to ensure that data collection efforts can be used to inform public health practitioners and policymakers.

CDC reviewed the published literature on menthol tobacco product policies and evaluations in the United States. This review revealed that there have been no other data collection efforts that match the extent of the current proposal. A 2022 qualitative review of local U.S. policies restricting flavored and menthol tobacco products found a positive association with reduced availability, marketing, and sales of policy-restricted products. However, the authors noted the need for further evaluation of implementation challenges and unintended consequences (e.g., switching to non-flavored tobacco products and purchasing in neighboring localities or online).[4]

CDC also reviewed all applicable national surveys (e.g., that collect information on tobacco-related measures) and found that the combination of information proposed to be collected does not currently exist within any national, publicly available data source. While some of the questions included on the web panel survey were previously validated as part of other data collection efforts, each proposed measure for this information collection was selected for the distinct purpose of collecting local-level data related to the impacts of menthol tobacco product sales restriction policies. Finally, this collection was and will continue to be discussed in an ongoing cross-agency flavored tobacco product evaluation workgroup, comprised of CDC and FDA. These workgroup discussions support the conclusion that no other evaluation efforts match the unique purpose and design of the proposed information collection.

A5. Impact on Small Businesses or Other Small Entities

The data collection request does not involve a burden to any small businesses or other small entities.

A6. Consequences of Collecting the Information Less Frequently

There are no consequences to collecting less frequently.

A7. Special Circumstances Relating to the Guidelines of 5 CRF 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

A8. Comments in Response to the FRN and Efforts to Consult Outside the Agency

Part A: PUBLIC NOTICE

A 60-day Federal Register Notice was originally published in the *Federal Register* on June 9, 2023, vol. 88 No. 111, pp. 37887 to obtain comments from the public and affected agencies. CDC received two substantive comments during that 60-day notice period and replied to each.
Due to initial 60 day FRN being in public display for over one calendar year, the 60-day Federal Register Notice was re-published in the *Federal Register* on September 3, 2024, vol. 89, No. 170, pp. 71280–71281 to obtain comments from the public and affected agencies. One substantive comment was received, and CDC provided a reply. See attachment 7a for this 60-day FRN publication. See attachment 7b for all three public comments and CDC's responses.

Part B: CONSULTATION

Deloitte Consulting LLP staff were involved in the development of this project from 2022 through the present.

Two consultants from the CDC's OSH participated in developing the information collection's data analysis plan, providing consultation on the statistical elements of the data analysis plan. Nine staff members from CDC OSH who were not part of the core evaluation team consulted on the information collection by participating in a pilot of the data collection tools. All nine OSH staff participated in piloting the web panel survey, while six of the nine OSH staff participated in piloting the community focus group interview guide.

Table 1. External Consultations

Name	Title	Affiliation	Phone	Email	Role
OUTSIDE CONSULTANTS					
Cathy Lesesne	Principle Investigator	Deloitte	*404-270-0513*	clesesne@deloitte.com	Project Lead & POC 2022 – present

Table 2. Consultations within CDC

Name	Title	Affiliation	Phone	Email	Role
Xu Wang	Health Economist	NCCDPHP/OSH	*770-488-1927*	wry3@cdc.gov	Provides consultation on data analysis
Iris Alcantara	Health Scientist	NCCDPHP/OSH	*770-488-4107*	ialcantara@cdc.gov	Provides consultation on data analysis
Henrietta Ross	Senior Health Scientist	NCCDPHP/OSH	*404-498-3200*	qbn3@cdc.gov	Participated in piloting of data collection tools
Laura	ORISE	NCCDPH		qej2@cdc.gov.	Participated in

Breithaupt	Fellow	P/OSH			piloting of data collection tools
Jennifer Keltz	Health Communications Specialist	NCCDPHP/OSH	*404-718-1460*	ycd6@cdc.gov	Participated in piloting of data collection tools
Jade Chambers-Blair	Public Health Analyst	NCCDPHP/OSH	*404-718-7512*	otx2@cdc.gov	Participated in piloting of data collection tools
Bob Vollinger	Senior Policy Analyst	NCCDPHP/OSH	*301-605-5841*	rav5@cdc.gov	Participated in piloting of data collection tools
Sundar Shrestha	Senior Economist	NCCDPHP/OSH	*770-488-4215*	gqm2@cdc.gov	Participated in piloting of data collection tools
Edward Irobi	Health Scientist	NCCDPHP/OSH		lwg7@cdc.gov	Participated in piloting of data collection tools
Tonya Williams	Health Scientist	NCCDPHP/OSH	*404-498-3026*	tis5@cdc.gov	Participated in piloting of data collection tools
Akimi Smith	Health Scientist	NCCDPHP/OSH	*404-498-2783*	oup3@cdc.gov	Participated in piloting of data collection tools

A9. Explanation of Any Payment or Gift to Respondents

Participants of the web panel survey will be rewarded with Qualtrics award points upon completion of the survey, in accordance with the rules and guidelines set by the Qualtrics panel. The number of award points received may vary depending on the compensation arrangement with Qualtrics. On average, the award points are equivalent to an estimated $10 per completed survey with a maximum of $15 per survey.

The community focus group participants will receive a $45 electronic Visa gift card upon completion of the focus group. The incentive amount of $45 is based on historical incentives previously approved by OMB for prior studies involving focus groups. Qualtrics will use the contact information provided by the participant to distribute the electronic Visa gift cards.

A10. Protection of the Privacy and Confidentiality of Information Provided by Respondent

To protect the privacy of participants, CDC will not capture any personal identifiable information (PII) or protected health information (PHI) from the web panel survey or focus group. All survey participants have previously opted to receive surveys through the Qualtrics platform. Qualtrics will have initial contact with participants through the recruitment procedures explained above. Qualtrics will anonymize the survey link and only collect IP addresses during fielding to monitor survey quality (e.g., ensuring that the same IP address does not complete multiple surveys). Once the information collection is complete, the IP addresses will be erased and unobtainable by anyone. The survey platform will have the name and email address of the individuals taking the survey so that they can provide compensation if they choose to complete the survey. However, neither Qualtrics nor CDC will have access to identifying information from the survey platform. CDC will only receive a de-identified dataset with survey responses for analysis.

All participants in the focus group will have previously opted to receive qualitative study opportunities through the Qualtrics platform. Participants recruited by Qualtrics have provided consent and have agreed to share PII with Qualtrics for focus group scheduling. Qualtrics stores all PII on a highly secured network and will not share PII with CDC. For individuals who are deemed eligible for the focus group and have consented to participate, Qualtrics will reach out via PII shared by the individual to schedule focus group discussions. For verbal communications, participants agree that anything communicated verbally is confidential and will not be shared publicly outside of the established use case. Qualtrics will not sell their information.

Electronic data (i.e., web panel survey data) will not include participant PII. Qualtrics will store electronic data on the Qualtrics cloud-based, password-protected, and encrypted platform. Project data are collected and stored via the same platform. Qualtrics is a FedRAMP-approved data collection product with the necessary security features for collecting, protecting participants, and storing and transporting data Qualtrics has been given Authority to Operate (ATO) for various functions across the federal government. Deloitte will access the password-protected area of the cloud-based platform that only shows the data for this survey effort. Additionally, through the Qualtrics platform, Deloitte will retrieve data via download to a local machine for analysis purposes after collection. Once data has been transferred and validated for accuracy, Deloitte will remove it permanently from the Qualtrics server.

Deloitte will store focus group audio and video recordings on a secure, password-protected cloud storage platform, accessible only through Deloitte's VPN server. Transcripts of the audio recordings will be de-identified before and during

analysis. Access to audio, video, and transcript files will be password-protected, and only authorized personnel at Deloitte will have access to the data. CDC will have access to the de-identified transcript files only. Audio recordings will be encrypted and transcribed using Zoom's transcription mechanism, which Deloitte will only use to validate the transcribed audio. Deloitte will store audio, video, and transcript files in Deloitte's password-protected cloud system. Deloitte will destroy focus group audio and video files once transcription is complete. Deloitte will delete files from the password-protected cloud and any local file storage.

CDC's data management policy regarding long-term storage and management will be adhered to. CDC will store the final de-identified dataset on CDC's government network, which is encrypted, password protected, and has restricted access. Deloitte will use encrypted email or data transfer software furnished by the government for transferring any data and files to CDC . A limited dataset of quantitative survey data may be made publicly available with restricted access within 30 months of data collection upon request. CDC does not plan to make a fully documented publicly available dataset on a website for download because there will be limited utility beyond this evaluation. CDC will not make the focus group transcripts public due to their limited utility and to ensure respondent confidentiality, however CDC does plan to publish aggregate findings.

A System of Records Notice (SORN) is not required for this data collection because records are not retrievable by PII. A Privacy Impact Assessment (PIA) is not required because CDC is not collecting PII electronically.

A11. Institutional Review Board (IRB) and Justification for Sensitive Questions

The IRB Board used by Deloitte, Solutions IRB, determined that this project is approved under the rules for expedited review. Deloitte's IRB letter of approval can be found in attachment 8a. In addition, the project underwent review by CDC's IRB and was approved; this letter of approval can be found in attachment 8b.

The risks of the information collection are low for the participating individuals. Most questions asked will be similar to what participants may expect during routine daily interactions. CDC will ask participants about their racial and ethnic identity, gender identity, and sexual orientation because this collection seeks to explore how menthol tobacco product sale restriction policies may impact racial and ethnic groups and LGBTQ+ communities. These questions will be asked since these populations are disproportionately targeted by tobacco industry marketing, and use menthol tobacco products at a higher prevalence than other populations.

To protect the anonymity of participants, CDC will not link survey nor focus group respondents' PII to their responses. Qualtrics (the data collection platform) will not retain any PII data from respondents (including IP addresses), so the risk of identifying an individual is low. Additionally, there is a risk that some of the questions may cause temporary discomfort for participants. There may be a temporary sense of shame associated with using tobacco products that may be increased by answering survey questions or discussing this topic with facilitators.

The web panel survey and the community focus group respondents will sign an electronic consent form prior to participating in the information collection process. This consent form states that participation in this collection is voluntary. The survey consent form alerts potential participants of the risk of temporary discomfort and reminds them that they can skip any question or end the survey without penalty. The focus group consent form reminds participants that they do not have to participate in any discussions that make them feel uncomfortable.

A12. Estimates of Annualized Burden Hours and Costs

This package is a new ICR request. CDC is requesting OMB approval for three years. There are no costs to respondents other than their time.

CDC conducted a power analysis to determine the sample size needed to detect a 7% difference between outcomes of interest among individuals living in cities with menthol restriction policies compared to individuals living in cities without these policies. The 7% effect size is based on a review of extant literature (see SSB section B2 for more information on this process). Based on this power analysis, this proposed ICR has a survey sample size of 5,366 individuals to detect this 7% difference.

Respondents in this evaluation will include 9,800 individuals screened for web panel survey eligibility. This recruitment number is based on Qualtrics’s estimate of the number of individuals who will need to be screened to reach a sample size of 5,366. These individuals will take one screener questionnaire. Screener questions will check for the following criteria: individuals over 18 years of age, individuals who live within the city limits of selected sites, and individuals who currently use or formerly used tobacco products. A total of 5,366 individuals who meet collection criteria and have signed up to participate in a web panel with Qualtrics will be asked to complete the web panel survey. Once 5,366 individuals have completed the survey, no further screening will occur.

Qualtrics will screen an additional 200 individuals for focus group eligibility. Screener questions will check for the following criteria: individuals over 18 years

of age, individuals who live within the city limits of a city with an implemented menthol tobacco sales restriction policy, individuals who have access to a device with video call capability, and individuals who currently use or formerly used tobacco products. Along with the three general population focus groups, CDC and Deloitte will hold three additional focus groups for racial and ethnic minority populations and three focus groups for LGBTQ+ individuals. As a result, focus group screener questions will also ask participants about their race, ethnicity, gender identity, and sexual orientation. Of those screened, 75 individuals who meet focus group criteria will participate in one of nine web-based, community focus group discussions. These 75 individuals have previously agreed to participate in web panels for qualitative studies through Qualtrics.

We calculated burden estimates based on the time needed to complete the survey screener questionnaire, the community web panel survey, the focus group screener questionnaire, and the virtual community focus group discussion. Based on testing of the survey screener questionnaire, the estimated burden response for the questionnaire is two minutes for each participating individual, and the total estimated burden hours for this information collection is 327 hours. The estimated burden response for the community web panel survey is 15 minutes for each participating individual. The estimated burden hours for this information collection for all groups is 1,342 hours. The estimated burden response for the focus group screener questionnaire is two minutes for each participating individual, and the total estimated burden hours for this information collection is 7 hours. The estimated burden response for the virtual community focus group is 60 minutes for each participating individual, and the estimated total burden hours for this information collection is 75 hours.

The total estimated annualized burden hours for this information collection are 1,751 hours.

Table A12A: Estimated Annualized Burden (Hours)

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Adults in the general population who currently use or formerly used	Survey Screener Questionnaire	9,800	1	2/60	327

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
tobacco living in the cities of interest					
Adults in the general population who currently use or formerly used tobacco living in the cities of interest	Community Web Panel Survey	5,366	1	15/60	1,342
Adults in the general population, racial and ethnic minority populations, and LGBTQ+ population who currently use or formerly used menthol tobacco living in the intervention cities of interest	Focus Group Screener Questionnaire	200	1	2/60	7
Adults in the general population, racial and ethnic minority populations, and LGBTQ+ population who currently use or formerly used menthol tobacco living in the	Community Focus Group	75	1	1	75

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
intervention cities of interest					
Total		15,441			1,751

The average hourly wage for individuals participating in this information collection is $40.58. We calculated this wage using the ACS 2021 5-year Selected Economic Characteristics table. We averaged the median incomes for each metropolitan statistical area included in this information collection and determined an hourly rate from that income average.

The total burden cost to information collection participants is $71,057.

Table A12B: Estimated Annualized Burden Costs

Type of Respondents	Form Name	Total Annual Burden Hours	Average Hourly Wage Rate	Total Respondent Labor Cost
Adults in the general population who currently use or formerly used tobacco living in the cities of interest	Survey Screener Questionnaire	327	$40.58	$13,270
Adults in the general population who currently use or formerly used tobacco living in the cities of interest	Community Web Panel Survey	1,342	$40.58	$54,459
Adults in the general population, racial and ethnic minority populations, and LGBTQ+ population who currently use	Focus Group Screener Questionnaire	7	$40.58	$284

Type of Respondents	Form Name	Total Annual Burden Hours	Average Hourly Wage Rate	Total Respondent Labor Cost
or formerly used menthol tobacco living in the intervention cities of interest				
Adults in the general population, racial and ethnic minority populations, and LGBTQ+ population who currently use or formerly used menthol tobacco living in the intervention cities of interest	Community Focus Group	75	$40.58	$3,044

A13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no other costs to participants aside from their time as shown in table A12B.

A14. Annualized Cost to the Federal Government

The average annual contractor cost for this data collection is $77,975 per year for a three-year total of $233,924.80. We determined this cost by calculating the value of the data collection component of the full contract. The full contract value over three years is $1,001,288.56, and the value of the contract during the data collection year is $637,464.00. We estimate that 20% of the contract work during the data collection year will support data collection, which values data collection at $127,493. Qualtrics fees for data collection, including the cost of incentives, are valued at $106,432, bringing the total cost of data collection to $233,925. We estimated the annual cost for staff wages for CDC to be $132,818 over a three-year period.

The average annualized cost to the Federal Government is $210,793, and the three-year cost is $601,092, as summarized in Table A.14-A.

Table A14.-A. Estimated Annualized Federal Government Cost Distribution

CDC Information	Annualized Cost	Total Cost Over Three-Year Period
Data collection (contractor)	$77,975	$233,925
Federal Staff*		
50% time for one FTE	$49,012	$147,036
20% time for two FTEs	$42,119	$126,357
25% time for two ORISE Fellows (2 years only)	$31,287	$62,574
5% time for two FTEs for analysis consultation	$10,400	$31,200
Total	$210,793	$601,092

*Pay rates may vary per year

A15. Explanation for Program Changes or Adjustments

This is a new request.

A16. Plans for Tabulation and Publication and Project Time Schedule

Quantitative Data

CDC will analyze quantitative data collected from the web-based survey, and will stratify observed outcomes (including differences between site types) by race, ethnicity, and LGBTQ+ identities and note any differences observed between subpopulations. CDC will test for statistical differences among categorical variables to determine if there are significant associations between variables of interest. Finally, CDC will use a series of weighted multivariate logistic regressions to determine which independent variables are associated with the primary outcomes of interest, adjusting for selected demographic covariates such as race, ethnicity, gender, and sexual orientation.

CDC will make the quantitative survey data available as a limited dataset with restricted access within 30 months of data collection. After data collection is completed, CDC will aggregate and analyze the data.

Qualitative Data

Qualitative analyses will use robust methods to identify themes. CDC will develop a qualitative codebook with inductive and deductive/a-priori codes based on the evaluation questions to conduct a thematic analysis. CDC will conduct qualitative coding in MAXQDA. To ensure inter-coder reliability, coders will independently code a set of transcripts using MAXQDA's code comparison feature to identify inconsistencies. After the initial coding process, CDC will analyze the data to identify recurring themes, which will be triangulated with the quantitative findings to provide additional context and a deeper understanding of the experiences of individuals, both from the general population and from specific subpopulations, who use menthol tobacco products following the implementation of policies that restrict menthol tobacco product sales.

CDC will not make the qualitative focus group data publicly available due to limited utility beyond the proposed evaluation and to ensure participant confidentiality. However, findings will be aggregated based on the thematic analyses for manuscript publication and potential incorporation into technical assistance documents.

Publication

Following the collection and analysis of the quantitative and qualitative data, CDC will disseminate the findings to key partners, including OSH and CDC leadership, leaders from other federal health agencies, government officials, policymakers, health departments, public health practitioners and researchers, advocacy organizations, community-based organizations, and others with interest in tobacco control policies. Dissemination products will include a PowerPoint slide deck to share the evaluation design and findings, two 1-2 pager high-level overview documents to describe the evaluation and its findings, conference abstracts and at least three manuscripts intended for publication in peer-reviewed journals.

Table A.16. Estimated Schedule for Project Activities

Activity	Timeline
Recruitment emails sent	1-2 weeks after OMB approval
Consent collected	Up to 3 months after OMB approval

Information collection	3 months after OMB approval
Data validation	Within 12 months after OMB approval
Data analysis	Within 12 months after OMB approval
Publication	Within 24 months after OMB approval

A17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is appropriate.

A18. Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification.

REFERENCES

[1] FDA, “FDA Proposes Rules Prohibiting Menthol Cigarettes and Flavored Cigars to Prevent Youth Initiation, Significantly Reduce Tobacco-Related Disease and Death”, Press Release, April 28, 2022. https://bit.ly/3Q70XF9

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