

**SUPPORTING STATEMENT FOR THE
NATIONAL QUITLINE DATA WAREHOUSE (NQDW)
(OMB No. 0920-0856, exp. 03/31/2019)**

PART A: JUSTIFICATION

Extension

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Submitted by:

Epidemiology Branch
Office on Smoking and Health
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention
Department of Health and Human Services

Refer questions to:

Lei Zhang
Epidemiology Branch
Office on Smoking and Health
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention
4770 Buford Highway, NE S107-7
Atlanta, Georgia 30341
(770) 488-1144
FAX (770) 488-5848
E-mail: fpv4@cdc.gov

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Goal of the study: Since 2010, the National Quitline Data Warehouse (NQDW) has collected a core set of information from the 50 U.S. states, the District of Columbia, Guam, and Puerto Rico regarding what services telephone quitlines offer to tobacco users as well as the number and type of tobacco users who receive services from telephone quitlines. The data collection was modified in 2015 to collect data from the The Asian Smokers' Quitline (ASQ) in addition to the other 53 states/territories provide data and included five new questions to the NQDW Intake Questionnaire to help CDC and states tailor quitline services to the needs of its callers.

Intended use of the resulting data: CDC uses the information collected by the NQDW extensively for ongoing monitoring, reporting, and evaluation related to state quitlines. Select data from the NQDW are reported online through the CDC's State Tobacco Activities Tracking and Evaluate (STATE) System website (<http://www.cdc.gov/statesystem>).

Methods to be used to collect data: Data on tobacco users who received service from state telephone quitlines is collected from all funded U.S. states, territories and the Asian Smokers' Quitline (ASQ) through the NQDW Intake Questionnaire. The NQDW Seven-Month Follow-up Questionnaire will be administered to tobacco users who received services from the ASQ only. Seven-month quit rates have been previously estimated for all Quitline callers except those that call the ASQ. Based on previous literature and a review of the follow-up evaluation data previously collected by the NQDW, seven-month quit rates are not expected to change significantly over time. Data on the quitline call volume, number of tobacco users served, and the services offered by state quitlines will be provided by state health department personnel who manage the quitline or their designee, such as contracted quitline service providers, using the NQDW Quitline Services Survey.

Subpopulation to be studied: The NQDW provides data on the general smoking population who contact their state quitlines, but also allows for collections of information about key subpopulations of tobacco users, such as pregnant women, uninsured, and people with mental illness, who contact state quitlines to better support cessation services.

How data will be analyzed: Simple descriptive data tabulations and trends are currently reported online through CDC's State Tobacco Activities Tracking and Evaluation (STATE) System website. More complex statistical analyses, including multivariate regression techniques will be utilized to assess quitline outcomes such as quitline reach, service utilization, how callers reported hearing about the quitline, and the effectiveness of quitline promotions and CDC's *Tips From Former Smokers* national tobacco education media campaigns on state quitline call volume and tobacco users receiving services from state quitlines.

A.1. CIRCUMSTANCES MAKING THE COLLECTION OF INFORMATION NECESSARY

CDC requests OMB approval to continue information collection for the National Quitline Data Warehouse (NQDW) (OMB No. 0920-0856, exp. 03/31/2019). OMB approval is requested for three years. CDC's authority to collect information for the NQDW is provided by the Public Health Service Act (Appendix A-1). Activities to improve quitline capacity are supported by funding through the American Recovery and Reinvestment Act of 2009 (Appendix A-2) and the Prevention and Public Health Fund of the Affordable Care Act (Appendix A-3).

The U.S. Surgeon General has concluded that the burden of death and disease from tobacco use in the United States is overwhelmingly caused by cigarettes and other combusted tobacco products (USDHHS, 2014). Cigarettes are the most commonly used tobacco product among U.S. adults, and about 480,000 U.S. deaths per year are caused by cigarette smoking and secondhand smoke exposure (USDHHS, 2014). And for every person who dies from smoking, 32 additional people suffer from at least one serious smoking-related illness (USDHHS, 2014). Despite these harmful effects, in 2016, 37.8 million U.S. adults were current cigarette smokers, and marked sociodemographic differences in smoking prevalence persist (CDC, 2018).

Tobacco dependence is a chronic disease that often requires treatment and multiple attempts to quit (Fiore, et al., 2008). During 2011–2013, a majority of adult smokers tried to quit in almost all states (CDC, 2015). To support quit attempts, quitlines are telephone-based services that provide callers with information, counseling, and referrals. Quitlines have been shown to be an effective, population-based intervention that increases successful quitting (Task Force on Community Preventive Services, 2011). The U.S. Public Health Services' *Clinical Practice Guideline: Treating Tobacco Use and Dependence – 2008 Update*, identified quitline counseling (telephone counseling that includes counselor-initiated calls or proactive counseling) as an evidence-based treatment that increased the odds of abstinence by approximately 60% (Fiore, 2008). State-based tobacco cessation quitlines have been shown to be cost-effective (CDC, 2004; Zhu, 2000) and overcome many of the barriers to tobacco cessation classes and traditional clinics because they are free and available at the caller's convenience.

Publicly funded state quitlines operate in every state, the District of Columbia, Guam, and Puerto Rico. As a result of a collaboration with NCI, callers can be automatically routed to their state quitline by calling 1-800-QUIT-NOW or Spanish-speaking callers can be automatically routed to Spanish-language services through 1-855-DEJELOYA. A national quitline for Asian languages of Korean, Mandarin, and Vietnamese is available and marketed directly to these communities in each of these languages.

The Centers for Disease Control and Prevention (CDC), Office on Smoking and Health (OSH) provides funding and technical assistance to Quitlines in all 50 states, the District of Columbia, Guam, Puerto Rico, and the Asian Smoker's Quitline (ASQ). Although Quitline services and operations vary across states and territories, some activities are based on common protocols that provide a framework for program monitoring and evaluation. A minimum data set (MDS) was developed collaboratively by the Quitlines and stakeholders including professional organizations and the CDC that serves as a core set of information reported by states.

Additionally, states have the option of adding state-specific questions and services to their intake or follow-up surveys that CDC does not require to be submitted.

During the most recent OMB approval period, 54 Quitlines reported caller intake to CDC through the NQDW. Additionally, the ASQ included follow-up data to CDC. In addition, each state- or territory-based Quitline submitted a quarterly services report which summarized its services, call volume, and caller characteristics.

A.2 PURPOSE AND USE OF INFORMATION COLLECTION

The specific aims of the planned data collection are to:

1. Nationally and by state, determine the population reach of quitlines.
2. Nationally and by state or territory, describe the characteristics of callers who are served by quitlines and determine whether high-risk populations (e.g., pregnant women, racial and ethnic minorities, low socioeconomic status, uninsured or medically underserved, and tobacco users with mental illness) utilize quitline services.
3. Estimate the number and proportion of callers who received treatment from the Asian Smokers' Quitline who successfully quit (7 month quit rate).
4. Nationally and by state, monitor and assess the services offered by state quitlines.

CDC will continue to use the information collected by the NQDW for ongoing monitoring and evaluation related to state quitlines, including routine tracking of quitline service metrics such as call volume and tobacco users receiving services from quitlines. CDC uses NQDW data to support provision of technical assistance and help identify best practices in quitline operations which can be used for program improvement. This data helps provide public health and education officials and the general public with accurate information about quit rate trends and use of quitlines, as well as inform program development and provide federal and state legislatures with information about the use and effectiveness of quitlines to inform resource allocation for cessation interventions.

In 2012, USDHHS initiated the U.S. Centers for Disease Control and Prevention's Tips From Former Smokers® (Tips®) campaign, the first-ever federally funded national tobacco education media campaign, to increase public awareness of immediate health damage caused by smoking and to encourage adult smokers to quit (www.cdc.gov/tips). Data collected by the NQDW serves an important role in helping CDC assess the effectiveness of the Tips® campaign in promoting the use of quitlines. In 2014, CDC provided approximately \$17 million through an Notice of Funding Opportunity (CDC-RFA-DP14-1410PPHF14) to 46 states, DC Guam, and Puerto Rico for a period of 48 months to ensure and support state quitline capacity, in order to respond to federal initiatives such as the CDC's Tips® campaign. A concept proposal has been submitted for a new Notice of Funding Opportunity to extend this effort for enhancement infrastructure open to all 50 states, DC, Guam, Puerto Rico and the ASQ estimate to start in 2019 for approximately \$18 million.

Starting in 2015, CDC is providing funding through the National State-based Tobacco Control Programs (CDC-RFA-DP15-1509) to continue submitting quitline data to the NQDW

for a period of 5 years. An essential element of this program includes cessation services provided through quitlines. *CDC's Best Practices for Comprehensive Tobacco Control Programs-2014* is an evidence-based guide designed to help states plan and establish effective tobacco control programs to prevent and reduce tobacco use (CDC, 2014a). The Guide's recommendations for state quitlines include increasing the level of quitline reach within each state to 6%-8%, providing a focus on populations experiencing tobacco-related disparities, providing nicotine replacement therapy through the quitline, and collaborating with health care systems to increase quitline referrals. The Affordable Care Act contains several provisions improving insurance coverage of evidence-based preventive services, including tobacco cessation. Health insurers and employers use state quitlines to provide evidence-based counseling services.

CDC will continue to make information collected by the NQDW available to federal and state governments, state tobacco control program managers, researchers, and the general public online through the CDC's State Tobacco Activities Tracking and Evaluate (STATE) System website (<http://www.cdc.gov/statesystem>).

Uses of Information Collection by Other Federal Agencies and Departments

The data collected as part of the NQDW are of interest not only to CDC, but also to other Federal agencies and departments. The Department of Health and Human Services, Center for Medicare and Medicaid Services, Food and Drug Administration, National Cancer Institute, Office of National Drug Control Policy and Substance Abuse and Mental Health Services Administration can use NQDW data to help inform regulatory, research, educational efforts, and demonstration projects focused on adult tobacco use cessation, especially related to addressing disparities in access to and use of cessation services.

Uses of Information Collection by Those Outside Federal Agencies

Data collected as part of the NQDW can be used in a variety of ways by state and local governments, researchers, voluntary health organizations, physicians, health educators, workplace wellness programs, and community outreach organizations:

- The legislative and executive branches of government can use NQDW data to evaluate existing quitline programs, and use the information to guide program investments.
- National data collected as part of the NQDW will provide an index against which state and local health agencies can compare their state quitline results.
- State and local health departments will use data collected as part of the NQDW as a guide in developing and monitoring state-based indicators for tobacco prevention and control.
- Family physicians, pediatricians, psychologists, and counselors may use data collected as part of the NQDW to provide up-to-date information on quit services and information.
- Health educators and workplace wellness programs may use data collected as part of the NQDW in their curriculum development to provide information on quitline services.

- Health plans/health care systems/insurers can use data collected as part of the NQDW to monitor the utilization and effectiveness of quitlines and compare the cost-effectiveness of quitlines with other covered quit services.
- Professional organizations can use data collected as part of the NQDW to make the case for the importance of tobacco cessation efforts and to monitor the progress of these efforts.

A.3 USE OF IMPROVED INFORMATION TECHNOLOGY AND BURDEN REDUCTION

Each state will determine the types of technology used in conducting intake interviews. The majority of states will use computer assisted telephone interviewing (CATI). At least one state will allow callers to conduct the initial intake interview online before they are referred to a live counselor. States will be encouraged to use information technology to reduce burden.

States currently have two options for submitting their individual-level data to CDC: either electronically submitting the data through CDC's secure FTP server site or mailing a copy of the data to CDC on a CD/DVD (Appendix B). CDC instituted online data submissions through a secure FTP server as a way to simplify and expedite data submission. Each state has its own user ID and unique password. The server is checked several times a week for files and the files are quickly removed after being downloaded. Technical assistance is provided to states to aid in the submission of data to the NQDW.

The NQDW Quitline Services Survey (Appendix C) is based on a fillable form-style Microsoft Word document. The survey consists of 17 questions, and the electronic form for the survey includes drop-down boxes, data entry fields, and checkboxes to help reduce data entry errors. In addition, CDC pre-populates the responses to questions 8-17 with the information the state reported for the previous quarter. This minimizes burden on survey respondents since states only need to make edits if changes occurred in the services being offered by the quitline since the last time the state responded to the survey.

A.4 EFFORTS TO IDENTIFY DUPLICATION AND USE OF SIMILAR INFORMATION

The North American Quitline Consortium (NAQC) is an international, non-profit membership organization. NAQC conducts an Annual Survey of Quitlines that CDC initially thought might serve some of the agency's data needs. However, NAQC's data is collected annually and based on states' fiscal years. CDC needs to have individual-level intake data quarterly and services data semiannually based on standard calendar periods to evaluate interventions (e.g. CDC Tips®) that may impact quitline utilization. In addition the data submitted to NQDW undergo a quality assurance process to maintain accuracy.

To minimize duplication of effort by CDC and NAQC, in 2011 CDC asked each state/territory for permission to share their quarterly NQDW Quitline Services Online Survey data for 2010 and 2011 with NAQC. Over 95% of the states agreed to this and we have shared these 2010 and 2011 NQDW Quitline Services Online Survey data with NAQC. NAQC can be

assured that these data are “clean” when they come from us because we have verified the various data points at various times with each state/territory. CDC views this as an opportunity to reduce the burden on states (as they will not need to complete similar surveys for CDC and for NAQC) as well as an opportunity to decrease duplication of similar data collection efforts by CDC and NAQC. CDC spent many person-hours on this effort and is willing to make a special effort in the coming years to again share data with NAQC. More recently, in 2015, CDC and NAQC were in close communication to ensure that CDC’s changes to the NQDW aligned with NAQC’s planned changes to the MDS. We plan to continue this communication on a regular basis in order to ensure the coordination of CDC’s and NAQC’s efforts in this area and to avoid duplication and minimize burden on states.

It is essential for CDC to have direct control and ready access to these data because CDC provides substantial funding to support state quitline activities and is accountable for the outcomes of these activities. CDC currently uses NQDW data for accountability of CDC funding, to track state quitline program performance, to answer questions posed by members of the U.S. Congress, and to respond to time-sensitive internal and external inquiries regarding the number of tobacco users served by quitlines. NQDW data can also be used to evaluate the effectiveness of CDC’s Tips® national tobacco education media campaigns on promoting calls to, and use of, state quitlines.

A.5 IMPACT ON SMALL BUSINESSES OR OTHER SMALL ENTITIES

The planned data collection does not involve small businesses or other small entities.

A.6 CONSEQUENCES OF COLLECTING THE INFORMATION LESS FREQUENTLY

The NQDW collects NQDW Quitline Services Survey data from states on a quarterly basis based on the calendar year. As such, CDC is obtaining data on call volume and the number of tobacco users receiving services by quarter. While CDC previously obtained data on services offered by quarter, CDC will now obtain these data semiannually and will publish NQDW data in the STATE System twice per year beginning in 2019. Collecting these data less frequently would adversely affect CDC's ability to release semiannual data from the NQDW on the STATE System in an ongoing, and timely, manner. Additionally, there is a large seasonality effect with respect to quitline utilization. Because of the seasonality of quitline utilization as well as the need to monitor the impact of the Tips® media campaigns on state quitline call volume and tobacco users registering for services from state quitlines, CDC believes it is important to collect information on call volume on a more frequent basis than annual data collection. Finally, during the past several years states have been changing their service mix (e.g., providing medication in some quarters and not others) during the course of the year, which confirms the need for data collection more frequently than annually. The NQDW data collection is intended as continuous data collection. As noted above, the resulting information will provide critical information at the state and national levels for ongoing evaluation and monitoring purposes. The CDC and quitline stakeholders use the NQDW data to demonstrate the role quitlines play in promoting tobacco use cessation, to measure the number of tobacco users being served by state quitlines, and to improve quitline operations, service quality, and access; more granular (quarterly/semiannual) data is necessary to inform the future of quitlines as well as future federal investments.

A.7 SPECIAL CIRCUMSTANCES RELATING TO THE GUIDELINE OF 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

A.8 COMMENTS IN RESPONSE TO THE FEDERAL REGISTER NOTICE AND EFFORTS TO CONSULT OUTSIDE THE AGENCY

A.8.a Federal Register Announcement

In accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-13 and Office of Management and Budget (OMB) regulations at 5 CFR Part 1320 (60 FR 44978, August 29, 1995)), CDC published a notice in the Federal Register announcing the agency's intention to request an OMB review of this information collection activity (Appendix A-4). This notice was published on November 6, 2018, Volume 83, Number 215, page 55548, and provided a 60-day period for public comment. During the notice and comment period, three public comments were received and responses provided (Appendix A-5). CDC responded to each commenter that their comments are being considered in future reviews.

A.8.b Consultations

CDC continues to consult with partner organizations including the North American Quitline Consortium (NAQC) to explore ways to increase utility of NQDW and reduce reporting burden. CDC has had ongoing conversations with NAQC regarding alignment of the data collection instruments as well as data sharing. CDC leaders also engaged quitline stakeholders including service providers to gain a better understanding of the evolving quitline service provision.

During 2017-2018, as part of a strategic planning process to inform OSH's future tobacco cessation priorities and activities, OSH solicited input on challenges and needs in this area from a wide range of stakeholders, including state tobacco control programs, national partners (including the North American Quitline Consortium), and quitline providers. This was done through a variety of methods, including calls, meetings, visits, and a federal register notice. This included seeking input on OSH's quitline activities, including the NQDW.

The information collected through this process was used to develop a strategic plan for OSH's future cessation activities and an operational plan for implementing these activities. The feedback gathered from stakeholders on the NQDW was used to identify several priorities for improving NQDW, including improving the quality of NQDW data, increasing the utility of this data, modernizing NQDW, and drawing on NQDW data to demonstrate the value of state quitlines.

Additional specific input, including plans for use of resulting data, were provided by the following representatives of federal agencies with an interest in tobacco as outlined in Appendix D.

A.9 EXPLANATION OF ANY PAYMENT OR GIFT TO RESPONDENTS

No payment or gifts are provided to respondents.

A.10 PROTECTION OF THE PRIVACY AND CONFIDENTIALITY OF INFORMATION PROVIDED BY RESPONDENTS

The Privacy Act does not apply to this information collection. CDC does not collect or receive information in identifiable form (IIF), nor can CDC retrieve the data by IIF data elements. CDC requests only a subset of de-identified client-level information, including some demographic data. The de-identified information is adequate for CDC/NQDW objectives.

Overview of the Data Collection System. The NQDW Intake questionnaire will collect data on tobacco use, intention to quit, previous success with quitting, and use of counseling and/or medications to facilitate or maintain quit. The Seven-Month Follow-up Questionnaire will also collect similar data but only for those who received services from the Asian Smokers' Quitline (ASQ). These topics are generally regarded as being no greater than minimally sensitive. Participation in the intake interview is voluntary but an intrinsic part of seeking services. Participation in the 7-month follow-up interview is completely voluntary. Through the

NQDW, CDC receives only de-identified common data elements. Intake data is only reported in aggregate in the CDC STATE System to prevent any inadvertent identification of callers' due to small cell sizes. The NQDW Quitline Services Survey gathers the types of information regarding services from state-based quitlines in tobacco control programs; therefore, this information is not considered sensitive. Therefore, all three data collections will have little or no effect on respondent's privacy.

Although the ASQ will collect information in identifiable form (IIF), such as name and telephone number, these data are for their operational purposes independent of what is requested to be reported to the NQDW and will be used to generate advance letters to ASQ quitline callers selected for the 7-month follow-up. The IIF will not be transmitted to CDC, and IIF will not be linked to response data.

Quitlines are state-based services. CDC provides cooperative agreement funding and technical assistance to help states/territories strengthen those services and to facilitate the collection of common data elements. States/territories devise their own strategies for delivering quitline services, and the Asian Smokers' Quitline (ASQ) devises its own strategies for contacting quitline callers for the NQDW Seven-Month Follow-up Questionnaire. Information on state-specific operating procedures is not requested as part of the NQDW. Nevertheless, safeguards will be put in place to ensure that all collected data remain secure (e.g., following protocols for minimum cell sizes for reporting on findings) (<http://www.cdc.gov/nchs/>).

Data for the NQDW Intake Questionnaire and Seven-Month Follow-up Questionnaire will be collected from callers primarily by telephone, including but not limited to Computer Assisted Telephone Interviews (CATI). Some intake data will also be collected via the web. We are recommending that states continue collecting the intake data using the same media that they are currently using. This is because the states have determined that these methods are the best to collect the data without disrupting the provision of services (the primary goal of the quitlines). Data from the NQDW Intake Questionnaire and Seven-Month Follow-up Questionnaire are typically submitted to CDC via the CDC's secure NQDW FTP server. However, states/territories and quitline service providers such as the ASQ also have the option of sending electronic data files to CDC via U.S. mail if the FTP site poses technical difficulties. The NQDW Quitline Services Survey will be completed electronically using a form-style Microsoft Word document. Completed surveys will be returned to CDC via email.

Items of Information to be Collected. The NQDW utilizes four instruments: the NQDW Intake Questionnaire (Appendices E-1 and F-1 to F-3); the NQDW Intake Questionnaire for the subset of participants who are calling for someone else (Appendix E-2 and F-4 to F-6) and the NQDW Seven-Month Follow-up Questionnaire for tobacco users who received services from the Asian Smokers' Quitline (Appendices G-1 to G-4), and the NQDW Quitline Services Survey (Appendix C). *CDC Best Practices for Comprehensive Tobacco Control Programs – 2014* recommends that quitlines should place specific focus on populations with disproportionate tobacco use (CDC, 2014a), and many state quitlines are either specifically targeting populations with disproportionately high tobacco use or provide additional quitline services to those populations (such as additional counseling or free quitting medications).

The NQDW Seven-Month Follow-up Questionnaire will be completed for tobacco users who completed an NQDW Intake Questionnaire and received a service from the Asian Smokers' Quitline (ASQ). The survey asks questions about quitline service satisfaction, whether or not the

caller has quit using tobacco, duration of quitting if applicable, use of products and/or medication to help quit, and use of non-quitline assistance to quit.

Respondents for the NQDW Quitline Services Survey are state health department personnel (e.g., state tobacco control managers, state cessation coordinators, state quitline managers – not private quitline service providers) or their designee, which might include quitline service providers such as the ASQ, in the 50 states, the District of Columbia, Guam, Puerto Rico, and for the Asian Smokers' Quitline. The survey asks questions about hours of service, available languages offered for counseling services, number of calls received, number of tobacco users who were provided with services by the quitline, eligibility criteria for receiving counseling through the quitline, provision of free quitting medications, and eligibility for and amount of free quitting medications offered.

Data Security. Precautions will be taken in how the data are handled to prevent a breach of privacy. Survey data and all identifying information about respondents will be handled in ways that prevent unauthorized access at any point during the study. To maintain security, only a sub-string of the telephone numbers associated with each completed call is included in the final data, so a respondent's answers cannot be connected to a specific person or telephone number. If there is the potential for the identification of these subject(s) in any reports produced by CDC, the data in these cells will be removed. Respondents will be told during the initial screener that the information they provide will be kept secure. All interviewers will be required to sign a non-disclosure agreement on the date of hire, which will be reinforced at training.

Consent. Verbal consent will be elicited from participants in the NQDW Seven-Month Follow-up with ASQ. Before each follow-up interview, the interviewer will read the informed consent script to each participant. The consent script describes the interview and the types of questions that will be asked on the actual survey. The consent script also indicates that participation is completely voluntary and that participants can refuse to answer any question or discontinue the interview at any time without penalty or loss of benefits. The interviewer will enter a code via the keyboard to signify that the participant was read the informed consent script and agreed to participate.

A.11 INSTITUTIONAL REVIEW BOARD (IRB) AND JUSTIFICATION FOR SENSITIVE QUESTIONS

IRB Approval

This information collection is a program evaluation activity, not research. IRB approval is not required.

Sensitive Questions

On the NQDW intake questionnaire, 27 of 32 questions are tobacco-related. Similarly, on the NQDW 7-month follow-up questionnaire, 26 of 28 questions are tobacco-related. The items are for the most part, not of a sensitive nature and are commonly found in surveys on tobacco use. Data on tobacco use are generally regarded as being no greater than minimally sensitive. Most importantly, each individual who completes the NQDW intake questionnaire is seeking assistance with tobacco cessation and providing intake data is part of service provision. The intake process and counseling protocols cannot be completed without asking about tobacco use history. Similarly, the NQDW Seven-Month Follow-up Questionnaire will be conducted among callers seeking services from the Asian Smokers' Quitline in order to assess the

effectiveness of its services. Although follow-up data are used to calculate a quit rate and determine what factors contribute to variability in quit rates, participation in the follow-up interview can identify needs for additional services, however, in the clinical context of the follow-up interview, these data are minimally or not at all sensitive.

The proposed NQDW intake questionnaire also includes ten demographic questions, one question about each of the following: gender, pregnancy status (for females), year respondent was born, zip code, level of education, race and ethnicity, insurance status (2 questions), and mental health. OMB considers questions about race and ethnicity to be sensitive, but not highly sensitive. None of the data reported on the NQDW Quitline Services Survey by CDC grantees is sensitive because these kinds of data are normally reported by grantees to maintain accountability in use of government resources. Therefore, the data collection will have little or no effect on a respondent's privacy. Nevertheless, safeguards will be put in place to ensure that all collected data remain secure.

A.12 ESTIMATES OF ANNUALIZED BURDEN HOURS AND COSTS

Estimated Burden Hours

OMB approval is requested for three years. The annualized estimates for the number of respondents and burden hours for this proposed OMB revision are summarized in Table A.12.a below. The burden table includes allocations for the time that the 50 states, DC, Guam, Puerto Rico, and the ASQ spend administering intake and follow-up interviews (ASQ only) to Quitline callers. The burden table also includes allocations for the 50 states, DC, Guam, Puerto Rico, and the ASQ to compile and submit aggregate files and service summaries to CDC.

Two versions of the NQDW Intake Questionnaire will be administered to callers through Computer-Assisted Telephone Interview (CATI). The complete questionnaire will be administered to callers who contact a quitline on their own behalf. The complete intake questionnaire will be administered by the 50 states, DC, Guam, and Puerto Rico (see Appendix E-1, in English). The estimated number of respondents is 488,845 based on 2015-2017 data. Callers who prefer to receive quitline services in Chinese, Korean, or Vietnamese will be referred to the Asian Smokers Quitline (see Appendices F-1 to F-3). The estimated number of callers for the ASQ is 1,935, based on ASQ data from 2016-2017. For all callers, the estimated burden per response for a complete intake call is 10 minutes.

An abbreviated version of the Intake Questionnaire will be administered to callers who contact the Quitline on behalf of another person (approximately 2.5%, which is an estimated 12,217 per year). Of these callers, 12,131 will be served through the 50 states, DC, Guam, or Puerto Rico (see Appendix E-2 in English) and 86 will be served through the ASQ (see Appendix F-4, F-5, and F-6 in Chinese, Korean, and Vietnamese, respectively). The abbreviated version consists of the first 4 questions of the intake interview. The estimated burden per response for these callers is 1 minute.

The Asian Smokers Quitline will administer a 7-Month Follow-up Questionnaire to callers who complete their intake call through the ASQ (see Appendix G-2 to G-4). An English language version of the 7-Month Follow-up Questionnaire is included for reference but will not be administered by the ASQ (see Appendix G-1). The estimated burden per response is 7 minutes. Although this is the first time the ASQ will administer the NQDW Seven-Month

Follow-up, we estimate the burden of seven minutes should remain consistent with the English language survey since we are using the same questionnaire. NQDW ASQ Seven-Month Follow-up Questionnaire interviews are collected primarily by telephone, including but not limited to Computer Assisted Telephone Interviews (CATI). The ASQ is the only service provider that will submit 7-Month Follow-up information to CDC. An estimated 1,587 tobacco users who called the ASQ for themselves and received services will complete the NQDW Seven-Month Follow-up Questionnaire. We are assuming that all of the estimated 1,935 tobacco users annually who call the ASQ for themselves and receive services from the ASQ will be recontacted and that the survey will have a response rate similar to the response rate of 82% for the Asian Smokers' Quitline (ASQ) published by Cummins et al. in 2015 ($1,935 \times 82\% = 1,587$).

The NQDW Quitline Services Survey (Appendix C) will be administered 4 times per year to state health department personnel (e.g., state tobacco control managers, state cessation coordinators, state quitline managers – not private quitline service providers) or their designee, which might include quitline service providers such as the ASQ, in the 50 states, the District of Columbia, Guam, Puerto Rico, and for the Asian Smokers' Quitline.

On a quarterly basis, the state tobacco control program manager or their designee such as quitline service provider like the ASQ, is responsible for providing CDC with a de-identified electronic data file containing data records for individuals who completed the NQDW Intake Questionnaire. In addition to the burden per respondent for completing the NQDW Intake Questionnaire, we also estimated and report the burden for creating electronic data files and submitting those to the NQDW. The burden for preparing and submitting the electronic data file for the NQDW Intake Questionnaire, either by uploading the electronic data file to CDC's secure NQDW FTP server or saving the electronic data file to a CD/DVD and mailing it to CDC, has been estimated as 1 hour per electronic data file submitted (4 times per year).

On an annual basis, a representative from the ASQ is responsible for providing CDC with an electronic data file containing de-identified data records for individuals who completed the NQDW ASQ Seven-Month Follow-up Questionnaire. These electronic data files are compiled from the ASQ's quitline data system, which is supported by state funding sources supplemented by cooperative agreement assistance from CDC. In addition to the burden per respondent for completing the NQDW ASQ Seven-Month Follow-up Questionnaire, we also estimated and report the burden for creating electronic data files and submitting those to the NQDW. The burden for preparing and submitting the electronic data file for the NQDW ASQ Seven-Month Follow-up Questionnaire, either by uploading the electronic data file to CDC's secure NQDW FTP server or saving the electronic data file to a CD/DVD and mailing it to CDC, has been estimated as 1 hour per electronic data file submitted (1 hour per year).

The NQDW Quitline Services Survey (Appendix C) collects aggregate information, on a quarterly schedule, about the services offered by the state quitline, rather than individual-level information from tobacco users receiving services from quitlines. CDC will request that the 50 U.S. states, the District of Columbia, Guam, Puerto Rico, and the Asian Smokers' Quitline (ASQ) complete the survey each quarter, for a total number of 54 respondents per quarter. The NQDW Quitline Services Survey instruments are state-specific fillable form-style Microsoft Word documents that CDC prepares each quarter for states to complete. The survey consists of 17 questions, and the electronic form for the survey includes drop-down boxes, data entry fields, and checkboxes to help reduce data entry errors. The first part of the survey (questions 1-7) consists of collecting respondent contact information and survey questions regarding the state's quitline call

volume, number of tobacco users served by the quitline, types of referral systems utilized by the state quitline, and number of referrals received by the quitline. The second part of the survey (questions 8-17) consists of questions regarding the services offered by the state's quitline: (a) the name of the state's quitline; (b) the phone numbers used by the state's quitline; (c) the quitline's hours of operation; (d) available counseling languages offered by the quitline; (e) eligibility criteria for receiving counseling from the quitline; (f) the amount of counseling offered by the quitline; (g) free quitting medications that are offered by the quitline; (h) eligibility criteria to receive free quitting medications from the quitline, and; (i) the amount of free quitting medications offered by the quitline. Quitline services offered do not typically change much from quarter to quarter for a given state, and consequently, responses to these questions tend to remain the same. To reduce burden on survey respondents, CDC pre-populates the responses to questions 8-17 with the information the state reported for the previous quarter. States are asked to review their previous responses to those questions and make edits if there were any changes in the services being offered by the quitline since the last time the state responded to the survey. The estimated burden per response is 20 minutes and is based on states' experiences completing these survey forms over the past five years.

The total estimated annualized burden to respondents is 82,477 hours.

Table A.12.a. Estimated Annualized Burden Hours

Type of respondent	Form Name	Number of respondents	Number of responses per respondent	Average burden per respondent (in hours)	Total burden (in hours)
Quitline callers who contact the quitline for help for themselves	NQDW Intake Questionnaire (English-complete)	488,846	1	10/60	81,474
	ASQ Intake Questionnaire (Chinese, Korean, or Vietnamese-complete)	1,935	1	10/60	323
	ASQ Seven-Month Follow-up Questionnaire	1,587	1	7/60	185
Caller who contacts the Quitline on behalf of someone else	NQDW Intake Questionnaire (English-subset)	12,217	1	1/60	204
	ASQ Intake Questionnaire (Chinese, Korean, or Vietnamese-subset)	86	1	1/60	2

Tobacco Control Manager or their Designee / Quitline Service Provider	Submission of NQDW Intake Questionnaire Electronic Data File to CDC	54	4	1	216
	Submission of NQDW (ASQ) Seven-Month Follow-up Electronic Data File to CDC	1	1	1	1
	NQDW Quitline Services Survey	54	2	20/60	36
				Total	82,440

The burden estimates for caller-level information collection are based on the length of the CATI interviews with callers. The majority of states have contracts with private-sector quitline service providers to manage the information collected through the CATI systems. The data management, cleaning and reporting activities conducted by quitline service providers are accounted for in their contractual agreements with states, and do not represent burden to the public. CDC allows states to use cooperative agreement funding to support these contracts. As quality improvement and cost containment measures, CDC provides substantial technical assistance to states to support and streamline these processes. Respondents for the NQDW Quitline Services Survey are tobacco control managers or their designees, which might include quitline service providers such as the ASQ. Their time is accounted for in the total burden estimate for the NQDW information collection.

A.12.b Estimated Annualized Cost to Respondents

There are no direct costs to the respondents in this planned data collection. Indirect costs to adult respondents can be calculated in terms of the time required to respond to the three questionnaires. For these calculations, we used the average hourly wage rate of \$26.84/hour (estimated mean of state, local and private industry earnings, U.S. Department of Labor). Reporting on the NQDW Quitline Services Survey is a requirement of The CDC core cooperative agreement for state tobacco control programs as well as CDC cooperative agreements that specifically provide funding for quitlines. These awards provide compensation for the cost of the state health department personnel’s time. The total estimated annualized cost to respondents is \$2,213,683.

Table A-12.b. Annualized Estimated Cost to Respondents

Type of respondent	Form Name	Number of respondents	Total Burden (in hours)	Average Hourly Wage	Total cost
.Quitline callers who contact the quitline for help for themselves	NQDW Intake Questionnaire (English-complete)	488,846	81,474	\$27	\$2,199,798.00
	NQDW (ASQ) Intake Questionnaire (Chinese, Korean, or Vietnamese-complete)	1,935	323	\$27	\$8,721.00
	NQDW (ASQ) Seven-Month Follow-up Questionnaire	1,587	185	\$27	\$4,995.00
Caller who contacts the Quitline on behalf of someone else	NQDW Intake Questionnaire (English-subset)	12,217	204	\$27	\$5,508.00
	NQDW (ASQ) Intake Questionnaire (Chinese, Korean, or Vietnamese-subset)	86	2	\$27	\$54.00
Tobacco Control Manager or their Designee / Quitline Service Provider (such as the Asian Smokers' Quitline)	Submission of NQDW Intake Questionnaire Electronic Data File to CDC	54	216	\$27	\$5,832.00
	Submission of NQDW Seven-Month Follow-up Electronic Data File to CDC	1	1	\$27	\$27.00
	NQDW Quitline Services Survey	54	36	\$27	\$972.00
Total					\$2,225,907.00

A.13 ESTIMATES OF OTHER TOTAL ANNUAL COST BURDEN TO RESPONDENTS OR RECORD KEEPERS

There will be no respondent capital and maintenance costs.

A.14 ANNUALIZED COSTS TO THE GOVERNMENT

CDC will have contract costs to create the database, clean and process the data, provide technical assistance to states on data collection, and report on the data of \$375,000 annually. Additional costs will be incurred indirectly by the government in personnel costs of staff involved in oversight of the study and in conducting data analysis. The direct annual costs in CDC staff time will be approximately \$136,313 annually.

<u>Activity</u>	<u>Yearly Costs</u>
<i>Annual Contract Costs</i>	
Data collection, processing and analysis	\$375,000
<i>Subtotal</i>	<i>\$375,000</i>
<i>Annual Personnel Costs (Federal Employee Time Cost)</i>	
5% time – GS14 FTE @ \$137,156	\$6,858
5% time – GS13 FTE @ \$119,121	\$5,956
5% time – GS13 FTE @ \$103,849	\$5,192
80% time – GS13 FTE @ \$103,849	\$83,079
20% time – GS12 FTE @ \$87,332	\$17,466
50% time – CCO – 04 FTE @ \$35,523	\$17,762
<i>Subtotal</i>	<i>\$136,313</i>
<i>Grantee Costs</i>	
5% of grantee’s program cost (Quitline FOA)	\$900,000
<i>Subtotal</i>	<i>\$900,000</i>
Total Annualized Cost to the Government	1,411,313

The annualized cost to the government for the study will be \$1,411,313. The 36-month cost to the government for the study will be \$4,233,939.

A.15 EXPLANATION FOR PROGRAM CHANGES OR ADJUSTMENTS

The total estimated annual burden hours for the proposed OMB revision are 82,440, which is 37 hours lower than the 82,477 estimated annual burden hours in the previous OMB approval period. This decrease is driven by the decrease in periodicity of the NQDW Quitline Services Survey from quarterly to semi-annually. Our update to this ICR includes a decrease in the number of respondents (-1,552) and an increase in the total burden (+1,767) based on an update of our estimates

A.16 PLANS FOR TABULATION AND PUBLICATION AND PROJECT TIME SCHEDULE

Data Tabulation Plans

Data will be tabulated in ways that will address the principal purposes outlined in A.3. Starting in November 2013, CDC began sharing tabulations using the NQDW data collected publicly online through the CDC's State Tobacco Activities Tracking and Evaluation (STATE) System website (<http://apps.nccd.cdc.gov/statesystem/Default/Default.aspx>) which contains a variety of current and historical state-level and national data on tobacco use prevention and control. CDC plans to continue sharing quarterly NQDW data tabulations from the NQDW data on the STATE system on an ongoing basis. Data is reported in aggregate to prevent involuntary disclosure due to small cell sizes at the individual level. Through the CDC's STATE System, website visitors can access a variety of detailed reports and data tables that present a state-level summary of NQDW data for a single quarter. Detailed reports available on the CDC's STATE System website that are based upon NQDW data include:

1. Quitline - Services Available
 - a. Hours of Operation and Available Languages
 - b. Counseling
 - c. Medications
2. Quitline – Service Utilization
 - a. Call Volume
 - b. Services Received
 - c. Caller Characteristics
 - d. How Callers Heard about Quitline
 - e. Types of Tobacco Products Used

CDC STATE System users can also access highlights reports that present state and national trends for several key measures from the NQDW data including quitline call volume, the number of tobacco users who received counseling and/or free quitting medications from quitlines, and the demographic characteristics and tobacco products used by individuals who completed an NQDW Intake Questionnaire. Finally, CDC STATE System users can access maps that present state-level standardized quitline call volume and reach measures. The STATE System is designed to integrate many data sources to provide comprehensive summary data on a state level and facilitate research and consistent data interpretation. The STATE System does not collect data and is simply a way for CDC to display data for public consumption in a user-friendly online environment. Data submitted to CDC for inclusion in the NQDW is cleaned, standardized, formatted, analyzed and shared with states for sign off and verification before being published online.

Publication and Dissemination Plans

CDC has, and continues to, extensively used the information collected by the NQDW for ongoing monitoring and evaluation related to state quitlines. CDC has also relied heavily on data from the NQDW to respond to frequent quitline-related queries from CDC management, the U.S. Department of Health and Human Services (USDHHS), state tobacco control programs, and legislators and policymakers. CDC plans to continue sharing and disseminating NQDW data from this data collection online through the CDC's STATE System website (<http://www.cdc.gov/statesystem>). CDC has also presented findings and results from the NQDW data collection at various meetings and conferences and plans to continue presenting NQDW data at a variety of meetings and conferences.

CDC plans to disseminate NQDW data through several mechanisms that will reach public health providers, clinicians who refer their patients to quitlines, quitline professionals and researchers. For example, data from the NQDW was included in CDC's Tobacco Control State Highlights 2012 report (CDC, 2013c). CDC anticipates presenting NQDW in similar reports in the future. CDC plans to release NQDW data through a variety of government publications, refereed journals, and annual conferences of national organizations focused on tobacco use, prevention and control, preventive medicine, health promotion, and epidemiology. Anticipated publications using NQDW data include:

- Examination of variations in quitline reach by race/ethnicity across U.S. states (Marshall et. al., 2016 <https://doi.org/10.1093/ntr/ntw281>)
- Examination of characteristics of ASQ callers, how they heard about the quitline, and their use of the service. (Kuiper et al., 2015 doi: [10.5888/pcd12.140584](https://doi.org/10.5888/pcd12.140584))
- Evaluation of the success of CDC's Tips® national tobacco education media campaigns that CDC has been running annually since 2012 on key quitline outcomes such as call volume and reach
- Proportion of quitline callers who report hearing about the quitline from a health
- Profiles of services offered by state quitlines and changes in quitline services offered over time

CDC has already begun drafting several of the manuscripts described above and plans to continue work on additional topics.

Time Schedule for the Project

The following represents our proposed schedule of activities for the NQDW, in terms of months after receipt of OMB clearance. Data collection is ongoing, and we anticipate obtaining OMB renewals to continue data collection until discontinuation.

Key project dates will occur during the following time periods for the data collection:

<u>Activity</u>	<u>Time Period</u>
Ongoing data collection for the NQDW Intake Questionnaire using approved protocols	As soon as possible after OMB clearance

Ongoing Seven-Month Follow-up Questionnaire interviews (only for Asian Smokers' Quitline) using approved protocols	As soon as possible after OMB clearance Individuals will be followed-up with 7 months after intake
States/Territories and ASQ submit electronic data files for the NQDW Intake Questionnaire	Quarterly and ongoing
ASQ submits electronic data files for the NQDW Seven-Month Follow-up Questionnaire	Annually and ongoing
States/Territories and ASQ submit NQDW Quitline Services Survey	Quarterly and ongoing
Process data and publish results	Quarterly and ongoing

A.17 REASON(S) DISPLAY OF OMB EXPIRATION DATE IS INAPPROPRIATE

The expiration date of OMB approval of the data collection will be displayed.

A.18 EXCEPTIONS TO CERTIFICATION FOR PAPERWORK REDUCTION ACT SUBMISSIONS

No exemptions from the certification statement are being sought.

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