SUPPORTING STATEMENT FOR THE

NATIONAL QUITLINE DATA WAREHOUSE

(OMB No. 0920-0856)

PART A: JUSTIFICATION

Revision

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ABSTRACT

CDC's Office on Smoking and Health requests a continuation of current OMB approval for operation of the National Quitline Data Warehouse (NQDW, OMB no. 0920-0856, exp. 7/31/2012). The NQDW was established in 2010 with funding provided by the American Recovery and Reinvestment Act of 2009. CDC proposes to continue information collection for three years with Affordable Care Act funding as well as other funding streams. Standardized information about quitline callers and the services provided to them will be collected from states and territories that receive funding from CDC for these purposes. CDC uses the information for program monitoring, evaluation, and improvement and is in the process of establishing an evaluation working group to further enhance uses of NQDW data. A value of the NQDW is that it is the first time there has been a place where quitline data from all 53 states/territories could be housed with individual-level intake and follow-up data as well as data on service provision. With the need of the NQDW established and the fact that this data collection effort does not duplicate any other federal data collection, CDC proposes minor changes to the original OMB clearance. Changes from the initial OMB approval include 1) implementation of an electronic reporting option for state submission of the NQDW Intake and 7-month Follow-up Questionnaires to CDC, 2) an increase in the estimated burden per response for the NQDW Quitline Services Online Survey, and 3) adjustments to the estimated number of respondents based on experience with the NQDW over the past two years. OMB approval of this Revision ICR is requested for three years.

A. JUSTIFICATION

A.1. CIRCUMSTANCES MAKING THE COLLECTION OF INFORMATION NECESSARY

This statement requests continued OMB approval of the National Quitline Data Warehouse (NQDW, OMB No. 0920-0856, exp. 7/31/2012), a central repository of information about tobacco quitline services provided by all 50 states, the District of Columbia, Puerto Rico, and Guam. The NQDW was established to assist in the evaluation of CDC-funded State and territorial quitlines and to provide a resource to states for ongoing program evaluation and improvement. The current ongoing data collection promotes standardized quitline caller intake and follow-up protocols and allows CDC to generate national and state-specific data on quitline services for the purposes of program monitoring, evaluation, and improvement. The legal justification for the information collection may be found in Section 301 of the Public Health Service Act (42 USC 241) in Appendix A-1. Quitline activities in the upcoming OMB approval period will be funded in part by the Patient Protection and Affordable Care Act (Appendix A-2), in follow-up to developmental activities for the NQDW which were made possible by the American Reinvestment and Recovery Act of 2009 (Appendix A-3). Prior to the infusion of Recovery Act dollars from 2010-2011, CDC supported the creation and enhancement of state quitlines as part of comprehensive tobacco control cooperative agreements awarded to states, but CDC did not compile client-level information on the services provided under those cooperative agreements. CDC's current and continued justification for maintaining the NQDW data

collection is based on the public health implications of tobacco use among adults within the United States, including costs of tobacco use, and specific mandates for CDC to monitor and/or reduce health risk behaviors and/or their associated health outcomes. The National Quitline Data Warehouse has had and will continue to have significant implications for the development of policies and programs aimed at increasing tobacco use cessation. OMB approval is requested for three years.

Public Health Implications of Tobacco Use. The Health Consequences of Smoking: A Report of the Surgeon General states that "despite the many prior reports on the topic and the high level of public knowledge in the United States of the adverse effects of smoking in general, tobacco use remains the leading preventable cause of disease, disability, and death in the United States" (USDHHS, 2004). CDC estimates that 443,000 people die from cigarette smoking or exposure to secondhand smoke each year (CDC, 2008), and another 8.6 million have a serious illness caused by smoking (CDC, 2003). For every person who dies from smoking, 20 more people suffer from at least one serious tobacco-related illness.

More than 126 million nonsmoking Americans, including children and adults, are regularly exposed to secondhand smoke (USDHHS, 2006). Secondhand smoke exposure causes serious disease and death, including heart disease and lung cancer in nonsmoking adults and sudden infant death syndrome, acute respiratory infections, ear problems, and more frequent and severe asthma attacks in children. Each year, because of exposure to secondhand smoke, an estimated 3,000 nonsmoking Americans die of lung cancer, more than 46,000 (range: 22,700–69,600) die of heart disease, and about 150,000–300,000 children younger than age 18 months have lower respiratory tract infections (USDHHS, 2006). Exposure to secondhand smoke increases the risk of coronary heart disease by 25 to 30 percent (IOM, 2009).

Despite these harmful effects, approximately 19.3% (45.3 million) of U.S. adults were still current cigarette smokers in 2010 (CDC, 2011a). Tobacco dependence is a chronic disease that often requires treatment and multiple attempts to quit (Fiore, et al., 2008). In each year, 52.4% of smokers try to quit (CDC, 2011b). In 2010, the proportion of smokers who tried to quit was 62.4% among persons aged 18--24 years, 56.9% among those aged 25--44 years, 45.5% among those aged 45--64 years, and 43.5% among those aged >65 years (CDC, 2011b).

Costs of Tobacco Use and Investment in Tobacco Control. The total economic cost to society of smoking--$96 billion per year in direct health-care expenditures and nearly $97 billion in productivity losses--is $193 billion per year (CDC, 2008). By comparison, investments in comprehensive, state-based tobacco prevention and control programs in fiscal year 2007 totaled $595 million, approximately 325-times less than the smoking-attributable costs.

Mandates to Monitor and/or Reduce Tobacco Use. The justification for the NQDW has strong Federal support. Sources of support include the Healthy People 2020 objectives (USDHHS, 2010), CDC's Strategic Plan for Tobacco Control for 2009 and Beyond, CDC's National Tobacco Control Program, CDC's ***Best Practices for Comprehensive Tobacco Control Programs,*** and CDC's ***Key Outcome Indicators for Evaluating Comprehensive Tobacco Control Programs.*** **In addition, new legislative mandates such as the Patient Protection and Affordable Care Act and the Family Smoking Prevention and Control Act of 2011 have increased the federal emphasis on tobacco control and the need to monitor and evaluate federal initiatives.**

Healthy People 2020. The federal government's Healthy People 2020 objectives chart the direction for public health activities for the current decade. Tobacco use is named in Healthy People 2020 as one of the HHS Secretary's 12 Leading Health Indicators. The Leading Health Indicators reflect the major public health concerns in the United States and were chosen based upon their ability to motivate action, the availability of data to measure their progress, and their relevance as broad public health issues. The Secretary also encourages states to take an even greater focus on tobacco use by monitoring patterns of use and smoking cessation attempts. The 2020 target is to increase recent smoking cessation success by adult smokers from 6% to 8% and quit attempts among youth from 58.5% to 64%. Of the 20 tobacco-related Healthy People 2020 objectives, information collected through the NQDW can contribute toward accomplishment and monitoring of the following (USDHHS, 2010).

TU-1 Reduce tobacco use by adults (aged 18 years and older).
TU-4 Increase smoking cessation attempts by adult smokers
TU-5 Adult success in smoking cessation

CDC Strategic Plan for Tobacco Control for 2009 and Beyond. One of CDC/OSH's strategic priorities starting in 2009 was to sustain and expand the capacity, reach, utilization, and effectiveness of quitline services. Collection of standardized state quitline data is enabling the CDC to determine current levels of quitline utilization and the quit rates for each program – information critical for benchmarking progress in increasing utilization and program effectiveness.

CDC's Best Practices for Comprehensive Tobacco Control Programs-2007. *Best Practices for Comprehensive Tobacco Control Programs* is an evidence-based guide designed to help states plan and establish effective tobacco control programs to prevent and reduce tobacco use (CDC, 2007). It calls for expanded quitline services in all states and conducting comprehensive evaluation of programmatic activities and measures of cessation outcomes. 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 planned data collection will enable CDC to determine if quitlines are following *Best Practices* guidelines and how well they are serving their targeted populations.

CDC's Key Outcome Indicators for Evaluating Comprehensive Tobacco Control Programs. *Key Outcome Indicators for Evaluating Comprehensive Tobacco Control Programs*

was created by CDC to help state and territorial health departments plan, implement, and evaluate state tobacco control programs (TCPs) (Starr et al., 2005). These goal areas can be used to understand the links between program activities, short-term, intermediate, and long-term outcomes; to identify outcomes; and assist in selecting key indicators. Key outcome indicators are specific, measureable tobacco control measures that represent achievement of a key public health outcome. Under new leadership at HHS and CDC, there is increased emphasis on tobacco control and, in particular, on using data for comprehensive program evaluation and program improvement of the National Tobacco Control Program.

Patient Protection and Affordable Care Act (ACA). One of the highest priorities emanating from the HHS's prevention plan for the *Affordable Care Act of 2011* is tobacco control, including efforts focused on cessation of which quitlines represent an effective and critical population-based approach. CDC distributed $8.7 Million in ACA 1 and 2 which allowed states, territories, and other tobacco control organizations to reach agreement on standardized data collection instruments and bring quitline data together into a centralized data warehouse (NQDW) to enhance program evaluation and improvement. The NQDW data collection effort provides important information to evaluate the Affordable Care Act expenditures and the reach and effectiveness of quitlines. Specifically, quitline data have been used to assess reach of the 12-week ACA-funded *2012 National Tobacco Education Campaign*. Also under ACA, $22.2 Million in Prevention and Public Health Funds will be awarded to ensure and support state quitline capacity, in order to respond to upcoming federal initiatives such as the National Tobacco Education Campaign.

Family Smoking Prevention and Tobacco Control Act. The Family Smoking Prevention and Tobacco Control Act (FSPTCA, signed into law on June 22, 2009) gave the Food and Drug Administration authority to regulate tobacco products. The FSPTCA reinforces the importance of the proposed data collection activity which gathers useful information to support the development of programs to assist tobacco users with quitting as information about the harms of tobacco use becomes more widely disseminated.

CDC's National Tobacco Control Program and the National Quitline Data Warehouse. The National Tobacco Control Program (NTCP) was established by CDC to reduce tobacco use and tobacco-related disease, disability, and death. The NTCP's four goal areas are: (1) The prevention of initiation of tobacco use among young people, (2) the elimination of nonsmokers' exposure to secondhand smoke, (3) the promotion of quitting among adults and young people, and (4) the elimination of tobacco-related disparities. Essential elements of this approach include state, community, and health systems interventions; cessation services provided through quitlines; media campaigns designed to counter tobacco industry marketing; policy development and implementation; surveillance; and evaluation. These interventions also target groups who are at highest risk for tobacco-related health problems due to disparities among demographic subgroups in the US in their tobacco use.

Quitlines are 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). Quitlines provide telephone-based tobacco cessation services that help tobacco users quit through individualized, tailored, counseling and self-help materials (Ossip-Klein & McIntosh, 2003). CDC has directly supported state quitlines since 2004 when CDC and the National Cancer Institute (NCI) created the National Network of Tobacco Cessation Quitlines Initiative to provide greater access to counseling for tobacco cessation to U.S. tobacco users. As a result of the Initiative, from 2004 through 2009, CDC created a special funding supplement for state quitlines. The quitlines were funded through a supplement to the NTCP cooperative agreements to states, with an average of $12,349,834 awarded per 12-month period ending in May 2009. Also, as part of the Initiative, NCI established a toll-free national portal number at 1-800-QUIT-NOW. This portal number automatically transfers callers to their state quitline. Quitlines now exist in all U.S. states, D.C. and five territories. CDC's current NTCP cooperative agreements include funds to support quitlines, but not as a separate supplement (i.e., quitline funding was integrated into overall program funding).

State tobacco cessation quitlines overcome many of the barriers to tobacco cessation classes and traditional clinics because they are free and available at the caller's convenience. They are also cost-effective because they offer multiple services centrally that often are unavailable locally (CDC, 2004; Zhu, 2000). In addition to the convenience and effectiveness of state quitlines, the demand for quitline services has been increasing over time. Most recent data show an increase from 328,795 incoming calls for 47 states in FY2006 (NAQC, 2008) to 920,790 for 50 states in FY2010 (NAQC, 2011). According to NQDW data, the number of incoming calls to state quitlines was 1,077,472 in 2010 (51 out of 53 grantees reporting) and 1,116,544 in 2011 (51 out of 53 grantees reporting). Unfortunately, quitlines remain under-funded and can not serve everyone who seeks to access them. According to CDC's Best Practices for Comprehensive Tobacco Control, approximately 6 to 8 percent of tobacco users potentially can be reached successfully by quitlines (CDC, 2007); however, primarily due to lack of resources, only 1 to 2 percent of tobacco users are currently using quitlines, based on our NQDW data.

In 2003, with leadership from the North American Quitline Consortium (NAQC) and other tobacco control organizations, the field reached agreement on a Minimum Data Set (MDS) consisting of (1) intake questions that should be asked of all callers and (2) follow-up questions that should be asked of a representative sample of callers 7-months post-intake who have both completed intake and received a quitline service. A recent NAQC publication states that, "If collected routinely and stored in a central repository these intake and 7-month follow-up data could be used to better understand quitline promotions, develop service benchmarks to improve services and better understand priority populations' utilization of quitlines. In addition, pooling these standardized data in a central location would allow quitlines to compare results across jurisdictions and provide an opportunity to study these issues on a scale no single state quitline is likely to study independently." (NAQC, 2009).

Beginning in 2010, CDC provided Recovery Act funds to states to enable: 1) a significant expansion of delivery of tobacco quitline services (estimated as a 38% increase in funding that would generate an estimated 80,000 additional quitters); 2) standardization of collection of data at intake and follow-up; and 3) sharing of these data with the CDC-operated National Quitline Data Warehouse. Prior to 2010, follow-up data were being collected in approximately 80% of

states. Also, in contrast to the intake data, prior to 2010 the schedule for conducting follow-ups, the number of follow-up attempts per individual, and the way follow-up data were collected varied across the states. As part of the NQDW, CDC proposed that all states conduct intake and seven-month follow-up data collections using standardized instruments adapted from the widely-accepted Minimum Data Set created by North American Quitline Consortium with ongoing contractual support from CDC. In addition, to document changes in capacity and services provided, each state recipient was and will continue to be required to complete a quarterly web-based questionnaire. Recovery Act outcome and output measures were reported through this web-based survey. Over the 24-month Recovery Act funding period, the National Quitline Data Warehouse received intake data (approximately 45,000 records per month). Follow-up data were collected from approximately 3,400 participants per month across all states, starting in month 8 (i.e., seven full months after the completion of the first intake questionnaire) of Recovery Act funding. CDC distributed approximately $44.5 million in Recovery Act funds to states to support tobacco quitlines.

The NQDW will continue in 2012 in most states and territories through the infusion of Affordable Care Act (ACA) funding (FOA number: RFA-DP09-90101SUPP10) to create additional tobacco quitters beyond what states and jurisdictions have projected to achieve in Recovery Act funded programs. Approximately $8.7 million (ACA 1 and ACA 2) is available for a period of 24 months to motivate tobacco users to quit through the use of quitlines and related health systems change and media efforts. The NQDW will also be continued into 2014 through the PPHF 2012 State Public Health Approaches for Ensuring Quitline Capacity Financed solely by 2012 Prevention and Public Health Funds (FOA Number: CDC-RFA-DP12-1214PPHF12). Approximately $22.2 million is available to 50 states, DC Guam, and Puerto Rico for a period of 24 months to ensure and support state quitline capacity, in order to respond to federal initiatives such as the National Tobacco Education Campaign.

One of the main NTCP goals is to promote quit attempts and help smokers who attempt to quit to do so successfully. The quitline intake and follow-up interviews assess a range of factors associated with cessation behaviors, including number of cessation attempts, length of time abstinent from tobacco use, symptoms of nicotine addiction, and use of effective cessation treatments including counseling and medications. Key outcome indicators for the NTCP that are addressed through the NQDW data collection are summarized in the table below.

The intake and 7-month follow up interviews are supported directly through indicators from Goal Area 3: Promoting Quitting among Adults and Young People. Together they address 4 outcome areas (7, 8, 11, and 13) and 10 unique indicators (see Table 1). Under Outcome Area 7: Establishment or Increased Use of Cessation Services, the planned data collection will generate data that fully meet the requirements of the three indicators that are measured at the state and national levels (3.7.1, 3.7.2 and 3.7.3) because these indicators are determined directly from quitline data. The three other outcome areas (8, 11, and 13) are best addressed through population-based data collections, but can be supplemented usefully by data from the planned data collection. The NQDW Quitline Services Online Survey will provide data on the total number of calls to quitlines and the total number of calls to telephone quitlines from users who heard about the quitline through a media campaign.

Table 1: Key Outcome Indicators for Evaluating Comprehensive Tobacco Control Programs

Outcome 7	Establishment or Increased Use of Cessation Services
Indicator 3.7.1	Number of callers to telephone quitlines
Indicator 3.7.2	Number of calls to telephone quitlines from users who heard about the quitline through a media campaign
Indicator 3.7.3	Number of calls to telephone quitlines from users who heard about the quitline through a source other than a media campaign
Outcome 8	Increased Awareness, Knowledge, Intention to Quit, and Support for Policies That Support Cessation
Indicator 3.8.3	Proportion of smokers who intend to quit
Indicator 3.8.4	Proportion of smokers who intend to quit smoking by using proven cessation methods
Outcome 11	Increased Numbers of Quit Attempts and Quit Attempts Using Proven Cessation Methods
Indicator 3.11.1	Proportion of adult smokers who have made a quit attempt
Indicator 3.11.2	Proportion of young smokers who have made a quit attempt
Indicator 3.11.3	Proportion of adult and young smokers who have made a quit attempt using proven cessation methods
Outcome 13	Increased Cessation Among Adults and Youth
Indicator 3.13.1	Proportion of smokers who have sustained abstinence from tobacco use
Indicator 3.13.2	Proportion of recent successful quit attempts

Privacy Impact Assessment Information

The NQDW Intake and 7-month Follow-Up questionnaires will collect data on tobacco use, intention to quit, success with quitting, and use of counseling and/or medications to facilitate or maintain quit. These topics are generally regarded as being no greater than minimally sensitive. The NQDW Quitline Services Online Survey gathers the types of information that normally would be gathered from grantees in maintaining accountability regarding expenditure of government funds; therefore, this information is not considered sensitive No personal client information is collected on any of the questionnaires because intake and 7-month follow-up data have been de-identified before they reach the NQDW. Through the NQDW, CDC receives only de-identified common data elements. Therefore, all three data collections will have little or no effect on the respondent's privacy. 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/).

Overview of the Data Collection System. Data for the intake and 7-month follow-up interviews 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). The quarterly service provider questionnaire will be completed only via the web. There are various methods of submitted data to CDC for the NQDW. Data from the NQDW Intake and 7-month follow-up questionnaires are submitted either via secure FTP server (60%) or via U.S. mail (40%). Data from the NQDW Quitline Services Online Survey is submitted mainly online (90%). However, there are some states who will submitted this data through other means (e.g., fax, email).

*Items of Information to be Collected***.** There are three instruments: the NQDW Intake questionnaire (Appendix E-1); the NQDW 7-month follow-up questionnaire (Appendix F-1); and the NQDW Quitline Services Online Survey (Appendix G-1). For the initial NQDW intake questionnaire, respondents (callers to the quitline) will be asked if they are calling for help in quitting themselves or to help someone else, how they heard about the quitline, whether this is their first time calling, their experience in using a variety of tobacco products, and intentions to quit.

The NQDW 7-month follow-up survey will be completed for a sample of callers who completed intake and received a service. 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. 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 services and for contacting quitline callers for the 7-Month Follow-Up questionnaire. State-specific operating procedures and data are not requested as part of the NQDW.

Respondents for the NQDW Quitline Services Online Survey are state health department personnel (e.g., tobacco control managers, quitline managers – not private quitline service providers) in the 50 states, District of Columbia, Puerto Rico, and Guam. The survey asks questions about hours of service, number of calls received (direct vs. referral), services received by callers, provision of services to populations disproportionately burdened with tobacco use, services provided as an integral part of the state's quitline, use of quitline counselors who speak languages other than English, eligibility criteria for receiving counseling through the quitline, differences in eligibility criteria for different levels of services, and provision of/eligibility for various medication services.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age. This information collection does not involve the identification of websites and website content directed at children under 13 years of age.

A.2 PURPOSE AND USE OF INFORMATION COLLECTION

Information collected as part of the NQDW has been used to demonstrate accountability to the Department of Health and Human Services, and is planned for inclusion in a Morbidity and Mortality Weekly Report publication, in CDC's 2012 Tobacco Control State Highlights Report and CDC's State Tobacco Activities Tracking and Evaluation (STATE) System. CDC has also been able to utilize NQDW data in a report on the number of quitters from CPPW funds

from NQDW Quitline Services Online Survey data (2010) provided to CDC's National Center for Chronic Disease Prevention and Health Promotion for their use in reporting to the Department of Health and Human Services. With the extension of our current approval, CDC will continue to be able to evaluate the impact of funding for quitlines and progress toward accomplishing national goals for increasing cessation. This data collection will continue to standardize intake and follow-up data collected by CDC-funded state quitlines and generate data on national and state levels for the purposes of program monitoring, evaluation, and improvement. Results will continue to be used by several other parts of CDC, by other Federal agencies, and by the states. The information will have broad use by state and local governments, nongovernmental organizations, and others in the private sector.

One of the primary goals of the NQDW data collection is for accountability of CDC funding which included $44.5 million in the American Recovery and Reinvestment Act/Communities Putting Prevention to Work (ARRA/CPPW) funding, $8.7 million as part of the Affordable Care Act funding, and the upcoming FY2012 funding of approximately $22.2 million that will be awarded to state health departments for tobacco cessation quitlines as part of the Public Health Prevention Funds initiative. State health departments can also use their CDC National Tobacco Control Program funding of approximately $61.8 million per year for tobacco cessation quitlines. CDC has used the NQDW data internally for tracking state quitline program performance for accountability purposes (i.e., CDC has used the NQDW data for internal, governmental purposes that would not be overtly apparent to external partners). For example, CDC has frequently used these data over the past 2 years to respond to time-sensitive internal and external inquiries regarding the number of tobacco users served by quitlines. We have also used the data internally to respond to requests for information from the OSH Program Services Branch (PSB) which is responsible for providing technical assistance to CDC-funded state tobacco control programs and ensuring that these state programs are providing efficient and effective programs to decrease the burden of tobacco use in the United States. This data has informed the PSB Project Officers' technical assistance to state tobacco control programs and enabled them to advise the states on optimal resource allocation. We have also used NQDW data to inform our planning for the potential impact on quitlines of FDA's proposed changes to the health warning labels on cigarette packs which will include the national quitline portal number (1-800-QUIT NOW), as well as in preparation for CDC's National Tobacco Education campaign (http://www.cdc.gov/Features/TobaccoEducationCampaign/) which had ads tagged with 1-800-QUIT NOW or www.smokefree.gov.

Specific Aims 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. By state, estimate the number and proportion of tobacco users who call a quitline who heard about the quitline through a media campaign and/or who were referred to a quitline by a health care provider.

3. Nationally and by state, describe the characteristics of callers who are served by quitlines and determine whether high-risk populations (e.g., racial and ethnic minorities and the

medically underserved) utilize quitline services.

4. Nationally and by state, estimate the number and proportion of callers who received treatment who successfully quit (quit rate).

5. Nationally and by state, determine improvements in quitline services (increased number of hours quitline is open to provide live pick-up of counseling calls, increased amount of services provided, increased number of languages in which quitline services are available, increased number of calls that are answered live, and increased number of health systems that utilize a quitline referral protocol) provided over a particular funding period or periods.

6. Nationally and by state, determine whether quitline reach and numbers who quit among quitline users increased over a particular funding period or periods.

Actual and Anticipated Uses of Results by CDC

Aside from CDC/OSH, data collected through the NQDW are likely to be used by several divisions within CDC's National Center on Chronic Disease Prevention and Health Promotion, including the Divisions of Community Health, Cancer Prevention and Control, Diabetes Translation, Heart Disease and Stroke Prevention, and Oral Health. Other Centers within CDC are likely data users, including the Center on Environmental Health where the asthma program resides.

Evaluation

- Report on accomplishment of Affordable Care Act measures as they apply to tobacco control.
- Report on the accomplishment of State Public Health Approaches for Ensuring Quitline Capacity - Funded by 2012 Prevention and Public Health Fund to address the anticipated increase in calls to quitlines due to federal media education campaigns, while expanding capacity and eligibility to ensure all callers receiving some form of assistance.
- Provide progress measurements related to four *HP 2020* objectives.
- Evaluate CDC's Performance Plan in compliance with Government Performance Results Act.
- Assess trends in quitline reach.
- Assess trends in cessation among quitline users.
- Assess the effectiveness of quitline promotions.
- Provide states currently operating a quitline with a national index against which to compare their state results on key short-, intermediate-, and long-term tobacco prevention and control outcome indicators.

Research Synthesis

- Present data on OSH's website and in peer-reviewed publications and at scientific meetings.

- Provide public health and education officials and the general public with accurate information about quit rate trends and use of quitlines.
- Provide U.S. data for inclusion in analyses and reports based on cross-national comparisons.
- Provide data that are relevant and can be incorporated into a variety of government publications, including reports from the Surgeon General's office.

Policy and Program Development

- Provide policy makers with information about quitting behaviors and quit trends so they can focus resources on cessation interventions.
- Provide state legislatures with information about the use and effectiveness of quitlines that should be preserved during a period of shrinking state budgets.
- Determine how media campaigns can influence the use of quitlines among adults and adolescents.
- Contribute a rich resource for use in supporting multi-agency Federal initiatives on the role and functions of quitlines.
- Assess the cumulative effects of multiple cessation interventions on tobacco use behaviors and quit rates among adults and adolescents.

Technical Assistance

- Help identify best practices in quitline operations which can be used for program improvement
- Assist states in interpreting their quitline data against a national benchmark.
- Provide evidence- and data-based technical assistance to state and local departments of health and education.

Actual and Anticipated Uses of Results 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. For example:

- Department of Health and Human Services has used National Quitline Data to evaluate the expenditure of Recovery Act funds. HHS may also use these data to provide progress measures at national and state levels on at least two Healthy People 2020 objectives and one of the 12 Leading Health Indicators.

- Center for Medicaid Services indicated that that the quitline data will be helpful to them as CMS has increased their focus on preventative measures. This data will give them a sense of how quitlines are serving medically underserved as well as the elderly. It will also give them a better sense of the services states are providing around tobacco use cessation. This information will be incorporated into their future planning around tobacco cessation interventions by their Division of Quality Outcomes and Evaluations.

- Food and Drug Administration will be able to use the data to assess the effectiveness of nicotine replacement therapies in quitline programs. FDA will also be able to use NQDW

data to monitor the impact of in health warnings on cigarette packaging (calls generated to 1-800-QUIT-NOW).

- National Cancer Institute can use NQDW to help inform its research, educational efforts, and demonstration projects focused on adult tobacco use cessation, especially related to addressing racial/ethnic disparities in access to and use of cessation services. NCI is likely to use National Quitline data to supplement its longstanding Tobacco Use Supplement to the Current Population Survey (TUS-CPS). In addition, NCI is likely to use quitline data in planning community-based intervention studies, especially those related to health disparities. National quitline data can also help NCI to monitor the use of their 1-800-QUIT-NOW programmatic activities.

- National Institute on Drug Abuse has expressed interest in creating a joint Program Announcement with NCI, CDC, and others to foster research utilizing the national quitline data. The research conducted through this joint Program Announcement would build on the work that NIDA, CDC, NCI, the Canadian Tobacco Control Research Institute, and Health Canada did in 2005-2007 around building a research agenda for quitlines.

- Office of National Drug Control Policy can use the national quitline data to report on tobacco use cessation rates among quitline users and determine the impact of a coordinated national media campaign on quit attempts among quitline users.

- Substance Abuse and Mental Health Services Administration can use quitline data to focus strategies related to tobacco use cessation that are incorporated into the agency's larger efforts focused on cessation of drug abuse. For example, the Center for Mental Health Services currently operates a program element on tobacco use cessation for adolescents and adults related to tobacco use cessation among children with mental illness and their families.

Use of Results by Those Outside Federal Agencies

Data collected as part of the NQDW are likely to 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:

- Policy makers in the legislative and executive branches of government are likely to use national quitline data to evaluate existing quitline policies and programs, and to develop new policies and programs based on evidence regarding proven cessation methods.

- 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 local quitline objectives for 2020.

- 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.

- Employers can use data collected as part of the NQDW results to create awareness of the dangers of tobacco use behaviors, quit services and information, assist in setting personal/corporate wellness goals, plan or modify existing programs, create/update staff development programs, and seek/target funding.

- 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 quit services.

- Professional organizations can use data collected as part of the NQDW to emphasize the importance of tobacco cessation efforts and monitor progress in tobacco control efforts.

Privacy Impact Assessment Information

The NQDW intake and 7-month follow-up questionnaires will collect data on tobacco use, intention to quit, success with quitting, and use of counseling and/or medications to facilitate or maintain quit. These subjects are generally regarded as being no greater than minimally sensitive. The NQDW Quitline Services Online Survey gathers the types of information that normally would be gathered from grantees in maintaining accountability regarding expenditure of government funds; therefore, no sensitivity is invoked. No personal client information is collected on any of the questionnaires because intake and 7-month follow-up data have been de-identified before they reach the NQDW. Therefore, all three data collections will have little or no effect on the respondent's privacy. 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 services and for contacting quitline callers for the 7-Month Follow-Up questionnaire. State-specific operating procedures and data are 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/).

A.3 USE OF IMPROVED INFORMATION TECHNOLOGY AND BURDEN REDUCTION

Each state will determine the types of technology used in conducting intake and follow-up interviews. The majority of states will use computer assisted telephone interviewing (CATI). At least one state also 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, but PPHF funds are meant to provide services rather than to fund hardware. There are no legal barriers to the use of information technology to reduce burden.

States currently have two options for submitting their individual-level data to CDC: either by mailing a copy of the data to CDC on a CD/DVD or by electronically submitting the data through CDC's secure FTP server site. Two years ago, the data submission procedures were

limited to submitting data on CD/DVD via U.S. Mail based on CDC security recommendations. However, at the request of states, CDC instituted online data submissions through a secure FTP server as a way to speed up data submission. Although there were some initial problems with the new FTP server system, these problems were quickly resolved quickly and the system has been working smoothly since then. Each state has its own user ID and unique password. The server is checked almost daily for files and the files are quickly removed after being downloaded. The only problems reported by states with the system now involve states not being able to access the FTP server because of firewall issues on their side. Technical assistance is provided to states to aid in the submission to data to the NQDW. We are also developing an up-to-date Reference Manual which will provide detailed instructions to states on data submission procedures. We believe that most of the technological difficulties have been resolved, as evidenced by the fact that we have received fewer CD/DVDs via U.S. mail as compared to the secure FTP server. For example, from 2010-2011, there were 137 individual-level data submissions on CD/DVD via U.S. mail compared to 202 individual-level data submissions received via the FTP server.

OSH is currently using MR-Interview (SPSS software) to administer the NQDW Quitline Services Online Survey to grantees. The survey typically asks 54 questions each quarter (Quarter 1, 2010 was the only quarter where more questions were asked due to an assessment of 7-month follow-up methodology questions). CDC is currently pursuing ways to condense the survey even further – e.g., by changing the format to table-style questions that ask about the provision of NRT/medications in a single question instead of in a series of questions. Future versions of the NQDW Quitline Services Online Survey will collect similar information in an even more efficient manner as we use an ongoing quality improvement process to enhance our data collection.

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

CDC conducts ongoing searches of all major health-related electronic databases, reviews related literature, consults with key outside partners and other experts, and maintains continuing communications with Federal agencies with related missions through the National Institutes of Health's Interagency Tobacco and Nicotine Research Interest Group (TANRIG). These efforts have identified one previous, unsuccessful attempt at collecting similar information. In 2005, NCI funded a pilot project through the University of California at San Diego's Quitline Data Repository. The pilot project was designed to collect and standardize quitline data from all states, but did not receive sufficient support from other states and as a result, the Data Repository only housed quitline data from California. The unsuccessful attempt, however, did increase the awareness of the benefits of collecting quitline data nationally and the need for standardization.

CDC has directly supported state quitlines since 2004 when CDC and the National Cancer Institute (NCI) created the National Network of Tobacco Cessation Quitlines Initiative. While CDC has encouraged the collection of intake and follow-up data in accord with the widely accepted NAQC's MDS for intake and follow-ups, prior to the inception of the NQDW CDC did not require grantees to conduct these surveys, and has not required grantees to share collected data with CDC as a requirement of funding. On a limited basis, evaluations have been conducted of quitlines operated by a few states (Tinkelman et al., 2007; Fellows et al., 2007; Hollis et al.,

2007; Maher et al., 2007; and Rabius et al., 2007). Under the Recovery Act cooperative agreements, states for the first time were expected to (1) administer standardized questionnaires for intake and follow-up interviews, (2) conduct follow-up interviews on a specified minimum number of participants (n=800), and (3) provide data to CDC on a standardized schedule. In addition, states were required to submit quarterly summary reports on services provided so types of services and changes in the overall constellation of services offered in a state may be considered in examining impact on utilization and quit rates. Previously, the overwhelming majority of states did not have the benefit of having detailed, state-specific data on patterns of tobacco use throughout the state; however, such data became available during the first year of the planned NQDW through the National Adult Tobacco Survey (NATS; OMB No. 0920-0828; expiration 10/31/2010).

NAQC conducts an Annual Survey of Quitlines that CDC initially thought might serve some of the agency's data needs. However, CDC was informed by NAQC that their procedure for external partners to obtain data from them consisted of submitting a formal written request for the data which would then be evaluated by a NAQC committee which would approve or deny the request. CDC did obtain a limited amount of data from NAQC in the past from this process. However, there is no guarantee that all data requests will be approved, and in fact, a request from a non-governmental organization for data was denied in the past (the group did resubmit and after another review by the committee the group did obtain the requested data). Because these data are critical for CDC for program accountability, we cannot depend on getting these data from a third party that could deny our request.

However, 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 next three years to again share data with NAQC.

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 inform CDC's Winnable Battles (i.e. public health priorities with large-scale impact on health and with known, effective strategies to address them - http://www.cdc.gov/winnablebattles/).

It would be inadvisable for CDC to rely on data obtained through a third party and not directly from the entities (state health departments) that CDC funds for these activities. Between 2010 and the present, CDC has funded at times 50 states, DC, Guam and Puerto Rico with

various funding mechanisms (ARRA/CPPW funding from 2010-2011 $44.5 million; Affordable Care Act funding from 2010-2012 $8.7 million; and a new Quitline FOA from 2012-2014 for $22.2 million) for quitline activities including the collection of data from the NQDW Quitline Services Online Survey, NQDW Intake Questionnaire, and/or NQDW 7-month follow-up questionnaire for the NQDW. In addition, the states under their FOAs have been required to submit these data to CDC.

CDC has strong and ongoing relationships with their grantees, the state health departments. The states are required as part of their work with CDC to submit information to CDC on the programmatic activities they conduct with their CDC funding. For quitline information, the states have been submitting this data to CDC for two years as part of the NQDW Quitline Services Online Survey. Within CDC these data are not only utilized by the technical assistants who operate the NQDW in the Epidemiology Branch of the Office on Smoking and Health (OSH) but by the Project Officers in the Program Services Branch in OSH. The Project Officers are the main point of contact for the state tobacco control programs and they monitor and advise them on the appropriate and most efficient and effective use of CDC funds. It would be counterproductive to have one group in CDC obtain information directly from states (i.e., the Project Officers) and to have another group, the NQDW TA's, go through a third party to obtain the data. We need the technical assistance provided by the two CDC groups to be seamless with direct communication with our grantees, the states. To summarize, given that OSH funds and provides technical assistance to state tobacco control programs, OSH needs to be able to go directly to states to obtain these data, rather than having to go through a third party.

In working with the NQDW Quitline Services Online Survey data during the past two years, CDC believes that it has greatly improved the quality of the data. In the beginning of the project, we thought that there would be few if any problems with the data since states had been reporting similar data to NAQC during the previous several years. In fact, we found that a number of states did not understand the survey questions (which were the same questions that had been in the field for a number of years) and we spent considerable TA time educating states on how to complete the survey. During this process we also assisted NAQC in identifying issues with their data. In addition, our TA's share each quarterly NQDW Quitline Services Online Survey with each state in an easy to understand report format. We want to make sure that what is going into the NQDW (in terms of data/information) is what the state intended. This process has proved to be helpful in improving the validity of the data, as states have reviewed this report and submitted corrections. By providing this type of ongoing quality checks, our process has resulted in more accurate data. The CDC TAs are now actively engaged in sharing a cumulative NQDW Quitline Services Online Survey report from 2010 and 2011 (another quality assurance measure) with states to show states how their responses vary from quarter to quarter We have received several corrections from states and these corrections have been made in the NQDW. By going through this process, data entering the NQDW represent a more valid picture of services in each state. We believe by collecting the data ourselves we will have a higher quality product. If we obtained data through a third party we would have no control over their quality assurance processes.

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 Online Survey data from states on a quarterly basis and based on the calendar year. As such, CDC is obtaining data on call volume and the number of tobacco users receiving services by quarter and these data are planned for inclusion in STATE System on a quarterly basis. In contrast, NAQC's data is collected annually and based on states' fiscal years. Because of the large seasonality effect with respect to quitline utilization, CDC believes it is important to collect information on call volume on a more frequent basis than annual data collection. Additionally, CDC uses this data to monitor changes in call volume and tobacco users receiving service in relation to discrete events (e.g., the National Tobacco Education Campaign which was conducted over 12 weeks in 2012 and is projected to be conducted again in 2013) and needs the data to be more granular than annual information. Finally, during the past year 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.

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

The data collection will be implemented in a manner consistent with 5 CFR 1320.5. No special circumstances are applicable to this proposed survey.

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

A.8.a Federal Register Announcement

The 60-day Notice of the proposed data collection was published in the Federal Register on April 4, 2012; Vol. 77, Number 65, pages 20400-20401 (Appendix B). Two public comments were received, including comments from the North American Quitline Consortium (Appendix C). In response to these comments, CDC added more detailed discussions to this information collection request which speak to the purpose and uses of the NQDW, clarify the rationale for the burden estimate, and the need to maintain the data collection under CDC sponsorship and supervision, with attendant technical assistance.

A.8.b Consultations

Over the period of at least a decade, to develop the current design for the NQDW, CDC consulted with states, the North American Quitline Consortium, various organizations involved

in the provision of quitline services (e.g., National Jewish Health; Alere Wellbeing), representatives of the scientific community, and representatives of various Federal agencies with an interest in tobacco.

OSH has sought, and continues to seek, state input on modifications to NQDW data collection procedures to minimize the burden these procedures impose on states and maximize the utility of the information collected. OSH continues to receive feedback from state and territorial grantees via various webinars, presentations at national meetings, and one-on-one TA conference calls. We have listened to this feedback and have modified our standard operating procedures in many ways in response to this feedback (as mentioned in examples throughout this OMB package).

CDC has directly supported state quitlines since 2004 when CDC and the National Cancer Institute (NCI) created the National Network of Tobacco Cessation Quitlines Initiative that provides greater access to counseling for tobacco cessation to U.S. tobacco users. CDC also provided technical assistance to states, in collaboration with NAQC and others, in development of intake and follow-up questionnaires, which over time have evolved into the currently accepted MDS. CDC has sought comments from states about the plan for the NQDW on several occasions. A telephonic conference call involving representatives of 40 states in February 2009 provided CDC with suggestions and feedback on the plan and design for the NQDW. Comments were again sought in conjunction with presentations made by CDC staff at the National Conference on Tobacco or Health in Phoenix, AZ, on June 9, 2009 and June 11, 2009.

CDC awarded a contract to the North American Quitline Consortium to provide guidance and input to the CDC on possible benefits of and challenges to gathering quitline data in a central location, such as the proposed Data Warehouse. Under this contract, NAQC convened a National Quitline Data Warehouse Work Group from February 2009 through June 2009 to help formulate NAQC's collective consultation and advice to CDC. CDC has had a close working relationship with NAQC, and since 2008, NAQC has served as a contractor to CDC with annual funding of approximately $265,000 per year. In this capacity, among several activities on the contract, NAQC has contributed to CDC's initiatives in the following ways:

- NAQC has further developed their Minimal Data Set to meet emerging data collection needs around quitlines including those that serve CDC's continued funding of state tobacco control programs for state quitlines. The NQDW uses standardized surveys based on the MDS for data collection.
- CDC has also paid for analysis and dissemination (on NAQC's website and through presentations) of NAQC's Annual Services Survey data.
- NAQC has also assisted CDC in providing technical assistance on the inception of CDC's National Quitline Data Warehouse (NQDW) by convening a group of leading state health department personnel who were asked whether a National Quitline Data Warehouse was in the best interest of the quitline community.
    - This NAQC group concluded that the National Quitline Data Warehouse was in the best interest of the US quitline community, that CDC was the appropriate home of such a data warehouse, and that any quitline data collection from state health departments should include appropriate contextual elements so that quitline data from states could be appropriately interpreted

(http://www.naquitline.org/resource/resmgr/reports-naqc/exploringanationalquitlineda.pdf).

- Since 2010, CDC has worked with NAQC to decrease the burden of quitline data collection to the state health departments. For example, CDC put out a special request to state health departments asking them if they would share their NQDW Quitline Services Online Survey data with NAQC so that NAQC did not have to collect this data separately from CDC. CDC was pleased that all but three states/territories agreed to share their data with NAQC and CDC subsequently sent all of the 2010 and 2011 NQDW Quitline Services Online Survey data that from the consenting states/territories to NAQC, as requested.

In addition, to provide expert guidance on data use and utility, CDC is in the process of establishing a NQDW evaluation working group. The purpose of the group is to obtain stakeholder feedback and expert opinion related to the NQDW for evaluation, monitoring, and program improvement. For example, this working group will be able to suggest key evaluation questions which can be answered using NQDW data. One of the goals of this working group will be to develop a detailed evaluation plan that addresses data analysis, quality assurance, and dissemination. The working group will consist of quitline evaluators and representatives from quitline service providers, NAQC, state tobacco control programs, and other federal agencies. This will provide an opportunity for CDC to obtain input on the specifics of NQDW data collection from the broad quitline community. The working group will be established in July 2012 and a report of the initial working group meeting available will be in September 2012.

Internally, CDC OSH has communicated with CDC's Division of Cancer Prevention and Control (DCPC) which has an overlapping interest in collecting and using some quitline data to supplement data on other cessation innovations for comparative effectiveness evaluations. Because of the timing, OSH was not able to collaborate with DCPC on their data collection effort, particularly as part of the NQDW. However, OSH is continuing to coordinate with DCPC as their project matures.

In addition, CDC also provided information to participate in a telephonic conference call in January 2010 of the NIH Tobacco and Nicotine Research Interest Group (TANRIG). Formed in January 2003, TANRIG currently has 48 members from NIH and other DHHS agencies, including 6 members from CDC. TANRIG's mission is to increase collaboration, coordination, and communication of tobacco- and nicotine-related research among NIH Institutes and Centers, and among partnering DHHS agencies outside of NIH. Members of TANRIG provided feedback on the plan and design for the NQDW. Additional specific input, including plans for use of resulting data, were provided by the following representatives of federal agencies with an interest in tobacco:

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Appendix D contains a list of individuals who participated in these consultations.

A.9 EXPLANATION OF ANY PAYMENT OR GIFT TO RESPONDENTS

States will have the option of using CDC funds for incentives to improve response rates, which historically have been in the 50% to 60% range in most states. Data from the initial NQDW Quitline Services Online Survey in Quarter 1, 2010 showed 5 states (9%) used incentives to increase participation in the NQDW 7-month follow-up questionnaire. States also will be encouraged to use other methods to improve response rates. State health department personnel or their designees will not receive any gift or payment for participation in the NQDW

Quitline Services Online Survey as this is part of their performance-related reporting requirements under the Affordable Care Act funding or any other funding streams.

A.10 ASSURANCE OF CONFIDENTIALITY PROVIDED TO RESPONDENTS

This information collection is a program evaluation activity, not research. IRB approval is not required. As part of the implementation of each quitline, prior to commencement of any data collection, the local project manager will be expected to review all procedures and provide trainings of interviewers as appropriate to safeguard respondents' privacy.

Privacy Impact Assessment Information

The NQDW intake and 7-month follow-up questionnaires will collect data on tobacco use, intention to quit, success with quitting, and use of counseling and/or medications to facilitate or maintain quitting. These subjects are generally regarded as being no greater than minimally sensitive. The NQDW Quitline Services Online Survey gathers the types of information that normally would be gathered from grantees in maintaining accountability regarding expenditure of government funds; therefore, no sensitivity is invoked. No personal client information is collected on any of the questionnaires because intake and 7-month follow-up data have been de-identified before they reach the NQDW. Therefore, all three data collections will have little or no effect on the respondent's privacy. States will follow their privacy laws to protect caller privacy before reporting to CDC. Once de-identified data reach the NQDW, CDC will put safeguards in place to ensure that all collected data remain secure (e.g., following protocols for minimum cell sizes for reporting on findings).

A. This submission has been reviewed by staff in CDC's Information Collection Review Office, who determined that the Privacy Act does not apply. Although information in identifiable form (IIF), such as name and telephone number, will be used by states to generate advance letters to 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.

B. 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 (cell count fewer than 30 records), 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.

C. Verbal consent will be elicited from participants. 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.

D. 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. Interviewers in the follow-up survey will tell respondents that "***Hello, my name is [NAME FILL]. I am calling from [EVALUATOR NAME FILL]. We are evaluating the quality of service provided by the [NAME OF YOUR QUITLINE FILL]. In order to improve the program, I would like to get your feedback on the services that you received. We will not use personal information (e.g., your last name, address, or phone number) to identify you. Your feedback will be summarized along with feedback provided by other people who have used the Quitline. You don't have to answer any question you don't want to, and you can end the interview at any time. Also, answering or choosing not to answer questions will not change the quitline services you can or will receive. The interview takes approximately 7 minutes and any information you give me will be kept secure."***

A.11 JUSTIFICATION FOR SENSITIVE QUESTIONS

On the NQDW intake questionnaire, 27 of 38 questions are tobacco-related [the first 5 questions are introductory in nature asking the following: 1) "How may I help you?", 2) "Are you calling for yourself or calling on behalf of or to help someone else?", 3) "How did you hear about the quitline?", 4) "Did you hear about 1-800-QUIT-NOW from any advertisements with smokers telling personal stories and tips about living with health problems?", and 5) "Is this your first call to the quitline in the past 12 months?"]. 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 of 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 7-month questionnaire is conducted among a representative sample of those seeking services as part of the effort to determine the effectiveness of cessation efforts. Although follow-up data are collected 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. The NQDW follow-up questionnaire goes beyond the NQDW intake questionnaire because it asks about services received. In the clinical context of the follow-up interview, these data are minimally or not at all sensitive.

The NQDW intake questionnaire also includes six demographic questions, one question about each of the following: gender, year respondent was born, zip code, level of education, race and ethnicity. OMB considers questions about race and ethnicity to be sensitive. On October 30, 1997, the Office of Management and Budget (OMB) published "Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity" (*Federal Register*, 62 FR 58781

- 58790). The 1997 standards reflect a change in data collection policy, making it possible for Federal agencies to collect information that reflects the increasing diversity of the U.S. population stemming from growth in interracial marriages and immigration. Under this policy, federal agencies are required to offer respondents the option of selecting one or more race responses from a list of five designated racial categories. Additionally, the standards provide for the collection of data on whether or not a person is of "Hispanic or Latino" culture or origin. Such standards also foster comparability across data collections carried out by various agencies. The race and ethnicity questions in the intake questionnaire follow all guidelines for the development of data collection questions, formats, and associated procedures to implement the 1997 standards.

None of the data reported on the NQDW Quitline Services Online 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 NQDW information collection involves administration of three questionnaires. The estimated burden for each questionnaire is based on data collected by CDC and input from states currently implementing state quitlines. The annualized estimates for the number of respondents and burden hours are summarized below.

The NQDW Intake Questionnaire will be administered to an estimated total of 535,456 callers per year across all states, the District of Columbia, Puerto Rico, and Guam. An estimated 510,768 callers will complete the intake interview from start to finish (see Appendix E-1(a)). The estimated burden for a complete intake interview is ten minutes. However, a small portion of callers (an estimated 24,688 per year) contact quitlines on behalf of other individuals. These callers will be asked to provide responses only to the first four questions on the NQDW Intake Questionnaire. Appendix E-1(b) shows the subset of questions that apply to these callers. The estimated burden for this subset of questions is one minute or less. All intake information is collected primarily by telephone, including but not limited to Computer Assisted Telephone Interviews (CATI).

The NQDW 7-Month Follow-up Questionnaire (Appendix F-1) will be collected from an annualized average of 28,900 callers across all states, the District of Columbia, Puerto Rico, and Guam. The estimated burden per response is seven minutes. Follow-up interviews are collected primarily by telephone, including but not limited to Computer Assisted Telephone Interviews (CATI). The burden for submitting 7-month follow up data to CDC has been estimated as 1 hour, this includes with uploading data to the secure FTP server or saving the data to a CD/DVD and preparing it to be mailed to CDC.

CDC will also collect the NQDW Quitline Services Online Survey (Appendix G-1) from all 53 states/territories funded for quitline services. This survey collects aggregate information, on a quarterly schedule, about the state quitline and services offered rather than individual-level

information. The estimated burden per response is variable. States that offer a larger array of support medications for smoking cessation are asked to respond to more questions than states that offer fewer medications. The majority of states (N=36) provide 2 medications--patch and gum--to quitline callers, and their average time to complete the NQDW Quitline Services Online Survey is 20 minutes. The estimated burden per response is based on their experience. In this Revision ICR, the estimated burden per response for the NQDW Quitline Services Online Survey is being increased from 7 minutes to 20 minutes.

On an annual basis, the Tobacco Control Manager is also responsible for sending CDC a de-identified summary of caller intake and follow-up data. The summary report is compiled electronically from the state's quitline data system, which is supported by state funding sources supplemented by cooperative agreement assistance from CDC. The summary report is based on the common NQDW data elements and is submitted to CDC electronically. Instructions for this submission are provided in Appendix E-1(c). The estimated burden per response for this submission is one hour. This includes with uploading data to the secure FTP server or saving the data to a CD/DVD and preparing it to be mailed to CDC.

The total estimated annualized burden to respondents is 89,035 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 response (in hours)	Total burden (in hours)
Quitline callers who contact the quitline for help for themselves	NQDW Intake Questionnaire (complete)	510,768	1	10/60	85,128
Caller who contacts the Quitline on behalf of someone else	NQDW Intake Questionnaire (subset)	24,688	1	1/60	411
Quitline caller who received a Quitline service	NQDW 7-Month Follow-up Questionnaire	28,900	1	7/60	3,372
Tobacco Control Manager	Instructions for Submitting Summary Caller Intake and Follow-up Data to CDC	53	1	1	53
	NQDW Quitline Services Online Survey	53	4	20/60	71

	Total	89,035

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. (States could use the following funding for formatting, and processing of data: Feb 2010-Feb 2012: $44 million dollars, Sept 2010 – Sept 2012: $8.7 million, and new June 2012 – June 2014: an estimated $22.2 million.) 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 Online Survey are tobacco control mangers, or their designees. 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/survey. For these calculations, we used the average hourly wage rate of $23.00/hour (estimated mean of state, local and private industry earnings, U.S. Department of Labor). Completion of the NQDW Quitline Services Online Survey is a requirement of the awards to states, the District of Columbia, Puerto Rico, and Guam. These awards provide compensation for the cost of the state health department personnel's time. The total estimated annualized cost to respondents is $2,046,581.

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

Type of respondent	Form Name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Average Hourly Wage	Total cost
Caller who contacts the Quitline on behalf of someone else	NQDW Intake Questionnaire	24,688	1	1/60	$23	$9,464
Other quitline callers, including those who contact the quitline for help for themselves		510,768	1	10/60	$23	$1,957,944
Quitline caller who received a Quitline service	NQDW 7-Month Follow-up Questionnaire	28,900	1	7/60	$23	$77,548
Tobacco Control Manager	NQDW Quitline Services Online Survey	53	4	20/60	$23	$1,625
					Total	$2,046,581

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

The data collection is funded under cooperative agreements to each of the states and Funding Opportunity Announcement No. CDC-RFA-DP09-90101SUPP10 (Affordable Care Act). The total award to all states, District of Columbia, Puerto Rico, and Guam is $8.7 million over a 24-month period. Half of the award (funding amount for 1 year) is $4.35 million. The annualized grantee's program cost for Affordable Care Act Funding is estimated at 10% of program cost for one year: $435,000. Funding for this data collection will also come from Funding Announcement No. CDC-RFA-DP12-1214PPHF12 (Public Health Prevention Fund). The total award to all states, District of Columbia, Puerto Rico, and Guam is $22.2 million over a 24-month period. Half of the award (funding amount for 1 year) is $11.1 million. The annualized grantee's program cost for Public Health Prevention Act funding is estimated at 10% of program cost for one year: $1.11 million (10% of program cost).

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 $413,200 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 $137,101 annually.

Activity	**Yearly Costs**
Annual Contract Costs	
Data collection, processing and analysis	$413,200
Subtotal	*$413,200*
Annual Personnel Costs (Federal Employee Time Cost)	
40% time – GS14 FTE @ $111,138	$44,455
40% time – GS13 FTE @ $88,350	$35,340
25% time – CCO – 06 FTE @$62,141	$15,535
100% time – CCO – 04 FTE @ $41,771	$41,771
Subtotal	*$137,101*
Grantee Costs	
10% of grantee's program cost (Affordable Care Act)	$435,000
10% of grantee's program cost (Public Health Prevention Fund)	$1,100,000
Subtotal	*$1,535,000*
Total Annualized Cost to the Government	**$2,085,301**

The annualized cost to the government for the study will be $2,085,301. The 36-month cost to the government for the study will be $6,255,903.

A.15 EXPLANATION FOR PROGRAM CHANGES OR ADJUSTMENTS

A number of changes that affect the burden estimate have been incorporated into this Revision request. First, we are adjusting the estimated number of respondents for the NQDW Intake Questionnaire. The initial NQDW clearance included an annualized estimate of 230,000 callers who would contact a quitline on behalf of someone else. This number was a misprint (it should have been 23,000) that significantly overestimated the number of callers in this response category. In the current Revision request, we estimate that an average of 24,688 callers per year will contact the quitline on behalf of someone else. This number is based on 2010-2011 NQDW data and includes a modest 15% increase for the expected effects of ACA/PPHF funding. There is no change to the estimated burden per response (one minute) on the NQDW Intake Questionnaire. However, due to the size of the technical adjustment in the number of respondents, there is a net decrease in the burden for this category of quitline callers.

There is no change in the estimated burden per response for callers who complete the quitline intake process on their own behalf (10 minutes). There is a net increase in the burden for this category due to an expected increase in the annualized number of respondents, due to increased support from PPHF funding sources.

There is no change to the estimated burden per response (7 minutes) for the NQDW 7-Month Follow-Up Questionnaire, or the estimated number of respondents participating in the 7-month follow-up.

There is no change to the estimated number of respondents for the NQDW Quitline Services Online Survey or the frequency of data collection. However, based on feedback from the respondents and information provided by NAQC, we are increasing the estimated burden per response from 7 minutes to 20 minutes. This adjustment results is a net increase in the total estimated burden for this component of NQDW data collection.

The summary effect of these changes is a net decrease in annualized burden.

Finally, OMB approval is being requested for three years instead of two years as in the initial ICR to establish the NQDW.

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

Tabulation Plans

Data will be tabulated in ways that will address the principal purposes outlined in A.3. The planned analyses to be conducted are described briefly below. Some of the objectives will also require use of data emanating from the OMB-approved National Adult Tobacco Survey (NATS) (OMB No. 0920-0828; expiration: 10/31/2012). CDC is currently requesting reinstatement of the NATS information collection.

1. Nationally and by state, determine the reach of quitlines. Absolute numbers and proportions of quitline callers who received a service (counseling and/or medication) out of all tobacco users reported on NATS will be calculated to address this objective.

2. By state, estimate the number and proportion of tobacco users who call a quitline who heard about the quitline through a media campaign and/or who referred to a quitline by a health care provider. Numbers, percentages, and confidence intervals will be calculated to address this objective.

3. Nationally and by state, describe the characteristics of callers who are served by quitlines and determine whether high-risk populations (e.g., racial and ethnic minorities and the medically underserved) utilize quitline services. Proportions of quitline callers who received a service (out of all tobacco users in a designated subpopulation), confidence intervals, cross tabulations, Chi-square analyses, and regression analysis initially will be conducted to address this objective.

4. Nationally and by state, estimate the number and proportion of quitline callers who received treatment who successfully quit (quit rate). Absolute numbers and proportions of quitline callers who received a service who quit, and confidence intervals will be calculated to address this objective.

5. By state, determine improvements in services provided over time. Improvements in services include increased number of hours quitline is open to provide live pick-up of counseling calls, increased amount of services provided (counseling and medication),

expanded the eligibility requirements of who will receive services, increased number of languages in which quitline services are available, increased number of calls that are answered live, and increased number of health systems that utilize a quitline referral protocol. Cross tabulations and Chi-square analyses will be conducted to address this objective.

6. Nationally and by state, determine whether quitline reach and number who quit among quitline users increased over time. Trend analyses by quarter will be used to address this objective.

Examples of the table shells that will be completed through analysis of the data are in Appendix H.

Publication and Dissemination Plans

CDC has used, and continue to use, the NQDW data extensively for internal accountability and program tracking, planning, and improvement purposes. Additionally, data and information related to the NQDW has been presented in the following forums:

- "Navigating the Complexities of Quitline Evaluation: Design and Methodology" Oral presentation at the 2010 American Evaluation Association conference – Lei Zhang, November 2010
- "National Quitline Data Warehouse" Oral Presentation at the 2011 NAQC Workgroup Meeting – Henraya McGruder and Nathan Mann, February 2011
- "Quitline Data for Program Evaluation" – Oral Presentation at 2011 CPPW Conference – Henraya McGruder, Paul Mowery, Jessie Saul , and Nathan, Mann, March 2011
- "CDC OSH's National Quitline Data Warehouse" - CDC internal Brown Bag presentation – Henraya McGruder and Nathan Mann, September 2011
- CDC's National Quitline Data Warehouse (NQDW): Progress to date, project management, technical assistance, and plans for data dissemination" Oral Presentation at the 2011 American Evaluation Association conference – Marti Engstrom, Henraya McGruder, Adriane Niare, Nathan Mann November 2011
- "CDC's National Quitline Data Warehouse (NQDW): Progress to date, project management, technical assistance, and plans for data dissemination" Poster presentation at the 2012 CPPW Conference – Henraya McGruder, January 2012
- "CDC OSH's National Quitline Data Warehouse – Data Presentation" - CDC internal Brown Bag presentation – Henraya McGruder, May 2012
- Presentations of OSH PSB All-state calls in March 2011, May 2011, September 2011, and January 2012 (Henraya McGruder)

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, 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.

NQDW data will be presented at the following upcoming meetings:

- Evaluation Ancillary at the 2012 National Conference on Tobacco or Health – August 2012
  "CDC's National Quitline Data Warehouse: Progress to Date, Project Management, Technical Assistance, and Plans for Data Dissemination"
- Poster presentation at the 2012 NAQC meeting – August 2012
  "The National Quitline Data Warehouse: Development, Implementation and Utilization"
- Poster presentation at the 2012 National Conference on Tobacco or Health – August 2012
  "CDC's National Quitline Data Warehouse"
- Webinar on NQDW – Fall 2012
  "CDC OSH's National Quitline Data Warehouse Data Presentation"

CDC plans to publish results initially through the MMWR publication, where a draft of a report summarizing 2010 NQDW Quitline Services data is summarized. These reports will be distributed to other Federal agencies, state and local health agencies, national health organizations, universities, and the general public. Data from 2010 NQDW Quitline Services Online Survey will also appear in the CDC's 2012 State Tobacco Control Highlights Report.

Additionally, CDC plans to disseminate these data through CDC's State Tobacco Activities Tracking and Evaluation (STATE) system (available at http://www.cdc.gov/tobacco.statesystem/), through which the public will be able to view tables, by state, on measures such as reach, quit rate, and hours of operation. The STATE System which was developed by CDC's Office on Smoking and Health (OSH) is an online system to display data that contains up-to-date and historical state level data on tobacco use prevention and control. 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. As with any new data collection system, data coming in to CDC from state health departments for inclusion in the NQDW has to be verified, standardized, cleaned, and analyzed before CDC can display the data on its website. CDC has spent the past two years working with states to verify the validity of the data, standardize data elements across the grantees, and then subsequently clean and analyze the data for inclusion in the STATE System. This process is nearing completion and CDC is currently waiting for the development of the web reporting templates on the STATE System which will display the data. Once both of these processes are completed, the NQDW data will be available on CDC's website through the STATE System. This should occur by December 2012.

It is also expected that a public-use data set will be released after CDC completes its initial program evaluation efforts. This time period is similar to the time period NIH gives its investigators before they share their data sets publically. CDC will also create an NQDW page on our CDC website that communicates pertinent information to our grantees and stakeholders regarding various types of information (i.e. data submission procedures, updates to current protocols, announcement of the NQDW Quitline Services Online Survey opening and closing dates, etc.). This website will include a Frequently Asked Questions (FAQ) page to help disseminate information and updates about the project. Lastly, CDC will conduct quarterly

webinars open to state tobacco control programs, quitline service providers, and other key stakeholders. During these webinars, we will provide updates about the Warehouse, answer questions, and obtain input and feedback from external stakeholders.

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. States will continue to use their existing, OMB approved forms through this data collection.

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

Activity	**Time Period**
Ongoing data collection using approved protocols	As soon as possible after OMB clearance
Initiation of 7-month follow-up interviews	7 months after intake
Quarterly services reports from state quitlines	Quarterly reporting
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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