SUPPORTING STATEMENT FOR THE

NATIONAL QUITLINE DATA WAREHOUSE

PART A

May 13, 2010

Submitted by:

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A. JUSTIFICATION

This statement supports a request for approval of a National Quitline Data Warehouse (NQDW) to assist in the evaluation of CDC's expenditure of Recovery Act (*America Recovery and Reinvestment Act of 2009*, see Appendix A-1) dollars on State quitlines and to provide a resource to states for ongoing program evaluation and improvement. This one-time data collection will 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. The National Quitline Data Warehouse will have significant implications for the development of policies and programs aimed at tobacco use cessation and reduction of tobacco use. Prior to the infusion of Recovery Act dollars, CDC has supported the creation and enhancement of state quitlines as part of comprehensive tobacco control cooperative agreements (i.e., the National Tobacco Control Program) awarded to states.

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; 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 U.S. in their tobacco use.

Quitlines are effective, population-based interventions that increase successful quitting (Task Force on Community Preventive Services, 2001). 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, 2005; Zhu, 2000). In addition to the convenience and effectiveness of state quitlines, the demand for quitline services has increased over time. Most recent data from 47 states in the U.S. show an increase from 328,795 intake calls in 2006 (NAQC, 2008) to 409,902 in 2008 (NAQC, 2009c). 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, 2008); however, primarily due to lack of resources, only 1 to 2 percent of tobacco users are currently using quitlines.

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 2009a).

CDC is providing 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 will 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 a CDC-operated National Quitline Data Warehouse. Quitline intake data are already being collected in all states. Follow-up data are being collected in approximately 80% of states. However, in contrast to the intake data, the schedule for conducting follow-ups, the number of follow-up attempts per individual, and the way follow-up data are collected vary across the states. NAQC recommends a single follow-up at seven months after intake. CDC proposes that all states conduct intake and seven-month follow-up data collections using standardized instruments adapted from the widely-accepted Minimum Data Set. In addition, to document changes in capacity and services provided, each state recipient will be required to complete a quarterly web-based questionnaire. Recovery Act outcome and output measures will be reported through this web-based questionnaire. Over the 24-month grant period, the Data Warehouse anticipates receipt of all intake data (approximately 45,000 per month). Seven-month, follow-up data will be collected from approximately 3,400 participants per month across all states starting in month 8 (i.e., seven full months after the first intakes) and continuing through month 24. CDC plans to distribute approximately $44.5 million in Recovery Act funds to states to support tobacco quitlines.

The current proposal comes at a particularly opportune time. 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 NTCP. One of the highest priorities emanating from the HHS's prevention plan for *the American Recovery and Reinvestment Act of 2009* is tobacco control including efforts focused on cessation of which quitlines represent an effective and critical population-based approach. The proposed data

collection effort provides important information to evaluate the Recovery Act expenditures and the effectiveness of quitlines. In addition, the *Family Smoking Prevention and Tobacco Control Act* (signed into law on June 22, 2009) gave the Food and Drug Administration authority to regulate tobacco products. This new regulation reinforces the importance of the proposed data collection activity which gathers useful information to support the development of policies regulating tobacco and other nicotine-containing products. In addition, state quitlines and other tobacco control organizations have reached agreement on standardized data collection instruments and they support CDC's efforts to standardize data collection and bring the data together into a centralized data warehouse to enhance program evaluation and improvement.

A.1. CIRCUMSTANCES MAKING THE COLLECTION OF INFORMATION NECESSARY

A.1.a Background

The legal justification for the survey may be found in Section 301 of the Public Health Service Act (42 USC 241) in Appendix A-2. Further justification for the NQDW data collection is based on three factors: (1) public health implications of tobacco use among adults within the United States; (2) costs of tobacco use, and; (3) specific mandates to monitor and/or reduce health risk behaviors and/or associated health outcomes.

A.1.a.1 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, 2008a), 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.

Although smoking prevalence has declined dramatically since its peak in the 1960s, the number of smoking-attributable deaths has remained relatively unchanged, primarily because of increases in population size (particularly among older age groups). Even with declines in the rates of various smoking-related diseases (e.g., coronary heart disease), the absolute number of deaths is increasing as the total population increases. In addition, cohorts of smokers with the highest peak prevalence have now reached the ages with the highest incidence of smoking-attributable diseases (CDC, 2008a).

Among U.S. adults 25 years of age or older, 59% of deaths are due to only two causes: cardiovascular disease (36%) and cancer (23%) (CDC/NCHS, 2008). During 2000 through 2004, smoking resulted in an estimated annual average of 269,655 deaths among males and 173,940 deaths among females in the United States (CDC, 2008a). The three leading specific causes of smoking-attributable death were lung cancer (128,922), ischemic heart disease (126,005), and chronic obstructive pulmonary disease (COPD) (92,915). Among adults aged

≥35 years, 160,848 (41.0%) smoking-attributable deaths were caused by cancer, 128,497 (32.7%) by cardiovascular diseases, and 103,338 (26.3%) by respiratory diseases (excluding deaths from secondhand smoke and from residential fires). Smoking during pregnancy resulted in an estimated 776 infant deaths annually during the period from 2000 through 2004. The average annual smoking-attributable mortality estimates also included 736 deaths from smoking-attributable residential fires (CDC, 2008b).

The harmful effects of smoking do not end with the smoker. 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, primarily 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 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 20.6% (46 million) of U.S. adults were still current cigarette smokers in 2008 (CDC, 2009a). Of these, 79.8% (36.7 million) smoked every day and 20.2% (9.3 million) smoked some days. By age group, the prevalence of smoking was lowest among those aged ≥65 years (9.3%), compared with those <65 years (persons aged 18–24 years [21.4%], aged 25–44 years [23.7%], and aged 45–64 years [22.6%]). Cigarette smoking is more common among men (23.1%) than women (18.3%).

Smoking prevalence has been declining. However, during the past five years, overall smoking prevalence among U.S. adults has remained virtually unchanged (20.9% in 2004, 20.9% in 2005, 20.8% in 2006, 19.8% in 2007 and 20.6% in 2008). Large disparities in smoking prevalence continue to exist among members of racial/ethnic minority groups and individuals of low socioeconomic status. In 2008, American Indians/Alaska Natives had a higher prevalence of current smoking compared with the other racial/ethnic groups (i.e., 32.4% among Whites). Cigarette smoking estimates are highest for adults with a General Education Development (GED) diploma (41.3%) or 9–11 years of education (35.7%), and lowest for adults with an undergraduate college degree (10.6%) or a graduate college degree (5.7%). Cigarette smoking is more common among adults who live below the poverty level (31.5%) than among those living at or above the poverty level (19.6%) (CDC, 2009a).

Tobacco dependence is a chronic disease that often requires treatment and multiple attempts to quit (Fiore, et. al, 2008). In each year, approximately 40 percent of the everyday smokers try to quit. In 2007, the proportion of current everyday smokers who tried to quit was 53.1% among persons aged 18--24 years, 39.9% among those aged 25--44 years, 38.1% among those aged 45--64 years, and 25.3% among those aged >65 years (CDC, 2009b). The majority of smokers who attempt to quit do not use recommended cessation methods (Fiore et al., 2008), and most of these untreated smokers relapse within the first 8 days after quitting; an estimated 24%--51% are abstinent at one week, 15%--28% are abstinent at one month, and 10%--20% are abstinent at three months (Hughs, et al., 2004). Of adult smokers who try to quit smoking each year, only 4%--7% are likely to be successful (Fiore et al., 2008). According to the *2008*

Treating Tobacco Use and Dependence Clinical Practice Guideline, smokers are more likely to quit successfully if they use evidence-based counseling or medication treatment than if they tried to quit on their own. Quitline counseling can increase the odds of abstinence by about 60% compared with quitting without assistance. Providing FDA-approved cessation medications with counseling increases cessation by 70% over counseling alone. Abstinence rates range from 16%-23% among quitline users and 30%-36% for those who use both quitline counseling and cessation medication (NAQC, 2009c).

A.1.a.2 Costs of Tobacco Use

Average annual smoking-attributable health-care expenditures from 2000 through 2004 were approximately $96 billion (CDC, 2008a). In addition to the direct health care expenditures, smoking accounted for an estimated 5.1 million years of potential life lost (YPLL) (3.1 million for males and approximately 2.0 million for females) annually, excluding deaths from smoking-attributable residential fires and adult deaths from secondhand smoke. Losses associated with YPLL resulted in $96.8 billion in productivity losses ($64.2 billion for males and $32.6 billion for females). Thus, 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, 2008a). 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.

A.1.a.3 Mandates to Monitor and/or Reduce Tobacco Use

The justification for the NQDW has strong Federal support. Sources of support include the Healthy People 2010 objectives (USDHHS, 2000), 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* guide, and CDC's report entitled *Key Outcome Indicators for Evaluating Comprehensive Tobacco Control Programs***.**

Healthy People 2010

One justification for the NQDW data collection can be found in Healthy People 2010 objectives, which chart the direction for public health activities for the current decade. Some of these objectives are being adjusted and re-targeted toward 2020 because relatively little progress has been made toward reaching some goals while others have been reached and exceeded. Of the 21 tobacco-related Healthy People 2010 objectives, the quitlines can contribute toward accomplishment of two of them (USDHHS, 2000): reduction of tobacco use and increase in cessation attempts (both objectives will be retained for Healthy People 2020).

27-1 Reduce tobacco use by adults (aged 18 years and older).
- 27-1a Cigarette smoking
- 27-1b Spit tobacco
- 27-1c Cigars
- 27-1d Other tobacco products

27-2 Reduce tobacco use by adolescents (by students in grades 9 through 12).

27-2a Tobacco products
27-2b Cigarettes
27-2c Spit tobacco
27-2d Cigars

The 2010 target is to reduce tobacco use by adults to 12% for cigarettes, 1.2% for cigars, and 0.4% for spit tobacco for all adult population groups. The adolescent target is to reduce all tobacco product use to 21% and specifically to 16% for cigarettes, 8% for cigars, and 1.0% for spit tobacco. Reduction of tobacco use by adults and adolescents is central to the NTCP program. The planned intake and follow-up interviews assess use of tobacco including cigarette smoking, cigars, chew/snuff, and other tobacco products (e.g., pipe). Healthy People 2010 also contains specific targets for cessation for adults and adolescents.

27-5 Increase smoking cessation attempts by adult smokers
27-7 Increase tobacco use cessation attempts by adolescent smokers

The 2010 target is to increase the proportion of adult smokers who stop smoking for at least one day because they are trying to quit from 41% to 75%, and for youth from 76% to 84%. 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.

Tobacco use is named in Healthy People 2010 as one of the HHS Secretary's 10 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 closer focus on tobacco use by monitoring patterns of use and smoking cessation attempts.

CDC Strategic Plan for Tobacco Control for 2009 and Beyond

Since 2009, one of the strategic priorities of CDC's Office on Smoking and Health (OSH) has been to sustain and expand the capacity, reach, utilization, and effectiveness of quitline services. Collection of standardized state quitline data, including the MDS and Recovery Act-related data, will enable 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 Guide to Best Practices for Comprehensive Tobacco Control Programs

The *Best Practices for Comprehensive Tobacco Control Programs* is an evidence-based publication designed to help states plan and establish effective tobacco control programs to prevent and reduce tobacco use. 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 Report

The *Key Outcome Indicators for Evaluating Comprehensive Tobacco Control Programs* publication was created by CDC to help state and territorial health departments plan, implement, and evaluate state TCPs. 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 characteristics of changes in tobacco control measures that represent achievement of a key public health outcome.

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 service provider questionnaire will provide data on the total number of calls to quitlines.

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

A.1.b Privacy Impact Assessment Information

The intake and 7-month follow-up data collection 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 service provider questionnaire 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 Warehouse. 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 private (e.g., following protocols for minimum cell sizes for reporting on findings) (http://www.cdc.gov/nchs/).

A.1.c Overview of the Data Collection System

Data for the intake and 7-month follow-up interviews will be collected primarily by telephone, including but not limited to Computer Assisted Telephone Interviews (CATI). Some intake data will also be collected via the web. (One state currently conducts nearly half of its intakes 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.

A.1.d Items of Information to be Collected

There are three instruments: the intake questionnaire; the 7-month follow-up questionnaire; and the quitline services questionnaire. For the initial 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 intention to quit.

The 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.

Respondents for the quitline services survey are tobacco control managers 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.

A.1.e 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

Data collected as part of the National Quitline Data Warehouse (NQDW) will be used to evaluate CDC's expenditure of Recovery Act dollars on state quitlines and progress toward accomplishing NTCP's goals for increasing cessation. This data collection will 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 also will 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.

A.2.a Purpose of Information Collection

The purposes 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 the 24-month funding period.

6. Nationally and by state, determine whether quitline reach and numbers who quit among quitline users increased over the 24-month intervention period.

A.2.b 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 for Chronic Disease Prevention and Health Promotion, including the divisions of Adult and 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 Recovery Act measures as they apply to tobacco control.
- Provide progress measurements related to five *HP 2010* 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.

A.2.c 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 will use 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 2010 objectives and one of the 10 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 that 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 the data to monitor their cessation efforts particularly if they include the 1-800-QUIT-NOW in cigarette packaging.

- National Cancer Institute can use National Quitline Data 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) (OMB NO. 0925-0368, exp. 3/31/2013). 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.

A.2.d 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.

A.2.e Privacy Impact Assessment Information

The intake and 7-month follow-up instruments 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 service provider questionnaire 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 Warehouse. 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 private (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 be allowing 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 Recovery Act 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.

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 a 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 pool 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 NAQC's widely accepted MDS for intake and follow-ups, CDC has not required grantees to conduct interviews, and has not required grantees to share collected data with CDC as a condition of the grant. On a limited basis, evaluations have been conducted of quitlines operated by a few states. (Tinkelman, D. et al., 2007; Fellows, J. L., T. Bush, et al., 2007; Hollis, J. F., T. A. McAfee, et al., 2007; Maher, J. E., K. Rohde, et al., 2007; and Rabius, V., K. J. Pike, et al., 2007). Under the current Recovery Act grants, States for the first time are 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 are 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 will become available during the first year of the planned NQDW through the National Adult Tobacco Survey (NATS; OMB No. 0920-0828; expiration 10/31/2010).

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 data collection is intended as a one-time data collection. As noted above, the resulting information will provide critical information at the state and national levels for 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 *Federal Register* notice of the proposed data collection was published in the Federal Register on March 1, 2010; Vol. 75, Number 39, pages 9224-9225 (Appendix B). CDC received three public comments. The first two are general comments on the data collection and the third comment includes suggestions to add two questions to the Intake Questionnaire. These questions include: 1) treatment of mental health and/or other disorders; and 2) chronic disease status. CDC considered the suggestions carefully. Because all the questions on the Intake Questionnaire are based on NAQC's MDS--which leaders and experts in the fields of tobacco use cessation and quitline intervention agreed upon and tested--no changes were made to the NQDW intake questions at this time. However, CDC is aware that NAQC has formed a workgroup of experts in mental health and addiction to begin formulating ideas on how these issues can be addressed by guidelines including potentially assessing these topics in questionnaires. CDC will continue to track the progress and outcomes of this workgroup and if needed revise the Intake Questionnaire. In addition, states have the option of adding their own questions as appropriate. For example, 27 states currently collect information on chronic disease status at intake. If a state's target populations are those with mental health and/or other chronic

conditions, the states are likely to add questions to assess these groups. A summary of public comments and CDC's response is provided in Appendix C.

A.8.b Consultations

To develop the current design for the NQDW, CDC consulted over the period of at last a decade with states, the North American Quitline Consortium, various organizations involved in the provision of quitline services (e.g., the American Cancer Society; Free and Clear), representatives of the scientific community, and representatives of various Federal agencies with an interest in tobacco.

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. In February 2009, a telephonic conference call involving representatives of 40 States 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, Arizona, 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.

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 is not able to collaborate with DCPC on their data collection effort, particularly as part of the NQDW. However, OSH will continue coordinating with DCPC as their plan for data collection 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. States also will be encouraged to use other methods to improve response rates. Service providers will not receive any gift or payment for participation in the service provider survey as this is part of their performance-related reporting requirements under the Recovery Act funding.

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.

A.10.a Privacy Impact Assessment Information

The intake and 7-month follow-up data collection 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 service provider questionnaire 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 by CDC on any of the questionnaires because intake and 7-month follow-up data will be de-identified before they reach the Warehouse. Therefore, all three data collections will have little or no effect on the respondent's privacy. States will follow their privacy laws to protect respondent privacy before reporting to CDC. Once de-identified data reach the Warehouse, CDC will utilize additional safeguards to ensure that all collected data remain private (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. States will utilize pre-existing record systems to facilitate follow-up.

B. Precautions will be taken in how the data are handled to prevent a breach of confidentiality. 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 dataset, 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 maintained in a

secure manner. 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 (see Appendix F-1). 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. 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 "Any information you give me will be kept private. The interview takes approximately 7 minutes." Interviewers will also tell respondents: "I will not ask for your last name, address, or other personal information that can identify you. You do not have to answer any question you do not want to, and you can end the interview at any time."

A.11 JUSTIFICATION FOR SENSITIVE QUESTIONS

On the intake questionnaire, 27 of 37 questions are tobacco-related. Similarly, on the follow-up questionnaire, 23 of 28 questions are tobacco-related (Appendix E-1/F-1). While an individual may be sensitive about answering such questions, 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 intake survey is seeking treatment and providing intake data to be utilized as part of the provision of services. The intake process and counseling protocols cannot be completed without asking about tobacco use history. Similarly, the 7-month questionnaire is conducted among a representative sample of those seeking services as part of the effort to determine the effectiveness of treatment. While 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 be regarded as therapeutic for those who have completed treatment. The follow-up questionnaire goes beyond the 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 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 services questionnaire by 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 are maintained in a secure manner.

A.12 ESTIMATES OF ANNUALIZED BURDEN HOURS AND COSTS

A.12.a Estimated Burden Hours

The planned information collection involves administration of three questionnaires over a two-year period. The annualized estimates for the number of respondents and burden hours are summarized below.

The Intake Questionnaire (Appendix E-1) will be administered to an estimated 730,000 callers (approximately 60,833 callers per month) across all states, the District of Columbia, Puerto Rico, and Guam. The estimated burden for completing the Intake Questionnaire interview is ten minutes. A portion of callers contact Quitlines on behalf of other individuals. The estimated burden for these callers is 1 minute or less, since they will be asked to provide responses only to the first three questions on the Intake Questionnaire.

Follow-up data will be collected from an annualized average of 28,900 callers across all states, the District of Columbia, Puerto Rico, and Guam (see Appendix F-1). The estimated burden per response is seven minutes. (Because follow-up must be conducted seven full months post-intake, administration of the Follow-up Questionnaire will begin in month 8 of the project period and continue through month 24. During months 8-24, information will be collected from approximately 3,400 respondents per month.)

The Tobacco Control Manager for each state, the District of Columbia, Puerto Rico, and Guam will be asked to complete a quarterly, web-based Quitline Services Questionnaire (see Appendix G-1) describing the services provided through their quitline. Five questions on this questionnaire only need to be collected once. The estimated burden per response is seven minutes.

The estimated burden for each questionnaire is based on data collected by CDC, NAQC, and input from States currently implementing state quitlines. There are no costs to respondents except their time. The total estimated annualized burden to respondents is 90,563 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)
Caller who contacts the Quitline on behalf of someone else	Intake Questionnaire	230,000	1	1/60	3,833
Caller who contacts the Quitline for personal use		500,000	1	10/60	83,333
Quitline caller who received a Quitline service	Follow-up Questionnaire	28,900	1	7/60	3,372
Tobacco Control Manager	Quitline Services Questionnaire	53	4	7/60	25
				Total	90,563

A.12.b Estimated Annualized Cost to Respondents

There are no direct costs to the respondents in this planned data collection. Indirect costs to adult respondents can be calculated in terms of the time required to respond to the three questionnaires. For these calculations, we used the average hourly wage rate of $23.00/hour (estimated mean of state, local and private industry earnings, U.S. Department of Labor). Completion of the Quitline Services Questionnaire 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 Tobacco Control Manager's time. The total estimated annualized cost to respondents is $2,082,951.

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	Intake Questionnaire	230,000	1	1/60	$23	$88,167
Caller who contacts the Quitline for personal use		500,000	1	10/60	$23	$1,916,667
Quitline caller who received a Quitline service	Follow-up Questionnaire	28,900	1	7/60	$23	$77,548
Tobacco Control Manager	Quitline Services Questionnaire	53	4	7/60	$23	$569
						$2,082,951

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-DP09-90101ARRA09. The total award to all states, District of Columbia, Puerto Rico, and Guam is $44.5 million over a 24-month period (total annualized cost of $22.25 million). The estimated annualized cost of data collection is based on 10% of the award, i.e., $2.23 million.

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. It is estimated that five CDC employees will be involved in the NQDW: one for 50% time ($44,650) and four for 20 % of their time ($23,000, $25,740, $25,740 and $26,832). The direct annual costs in CDC staff time will be approximately $145,962 annually. CDC will also have contract cost of $750,000 annually for tasks that include creating the database, cleaning and processing the data, providing technical assistance to states on data collection, and reporting the data.

The total cost for the study over a 24-month period, including the contract cost and federal government personnel cost is $6,251,924 The annualized cost to the government for the study will be $750,000 + $2,230,000 + $145,962 = $3,125,962.

Activity	**Costs**
Contract Costs	
CDC/OSH website construction/maintenance	$90,000
Specifications development, programs to test specifications, evaluation plan, help getting data into database, and cleaning data	$107,500
Analyzing and reporting data	$37,500
Subtotal, Contract Activities	$235,000
Personnel Cost	
Informatics Fellow 2nd yr salary	$41,000
Senior Scientist	$225,000
Senior Scientist/Medical Officer Consultant @$150.00/hour	$29,000
Two junior scientists for state TA/data analysis	$220,000
Subtotal, Contract Personnel	$515,000
Grantee Cost	
10% of grantee's program cost	$2,230,000
Subtotal, Grantee Cost	$2,230,000
Federal Employee Time Cost	
20% time for two FTEs @$61.88/hour	$51,480
20% time for one FTE @ $64.50/hour	$26,832
20% time for one FTE @$55.29/hour	$23,000
50% time for one FTE @ $42.93/hour	$44,650
Subtotal, Federal FTEs	$145,962
Total Cost to the Government	**$3,125,962**

A.15 EXPLANATION FOR PROGRAM CHANGES OR ADJUSTMENTS

This is a new collection of information and therefore, there are no program changes or adjustments.

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

A.16.a Tabulation Plans

Data will be tabulated in ways that will address the principal purposes outlined in A.2. 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: 10/31/2010).

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 the 24-month funding period. 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 the 24-month intervention period. 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.

A.16.b <u>Publication Plans</u>

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. CDC plans to publish results initially through the *MMWR*, which will be distributed to other Federal agencies, state and local health agencies, national health organizations, universities, and the general public. The public will be able to make queries through CDC's State Tobacco Activities Tracking and Evaluation (STATE) system (available at http://apps.nccd.cdc.gov/statesystem/), through which they will be able to view tables, by state, on the Recovery Act measures, such as reach, quit rate,

and hours of operation. It is also expected that a public-use data set will be released after CDC completes its initial program evaluation efforts, similar to the time period NIH gives its investigators before they turn over their data sets.

A.16.c 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 will begin as soon as possible after receipt of OMB approval. States will continue to use their existing, non-standardized data collection methods until OMB approval for the new, standardized data collection forms. The urgency of receipt of timely clearance is driven by the desire to have OMB clearance as soon as possible to further standardize data collection.

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

Activity	**Time Period**
Recovery Act funding period	January 1, 2010 – December 31, 2011
Initiation of data collection using new protocols	As soon as possible after OMB clearance
Initiation of 7-month follow-up interviews	7 months after initiation of data collection using new protocols
Quarterly services reports from state quitlines	Quarterly reporting
Process data and publish results	Ongoing during the period of OMB approval for data collection; additional analysis and reporting on the complete dataset will continue after completion of data collection

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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