State Medicaid Tobacco Coverage Survey

OMB No. 0920-0691 (exp. 8/31/2008)

Supporting Statement – Part A

Request for Reinstatement

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TABLE OF CONTENTS

A. Justification

A.1. Circumstances Making the Collection of Information Necessary
A.2. Purpose and Use of Information
A.3. Use of Improved Information Technology and Burden Reduction
A.4. Efforts to Identify Duplication and Use of Similar Information
A.5. Impact on Small Business or Other Small Entities
A.6. Consequences of Collecting the Information Less Frequently
A.7. Special Circumstances Relating to Guidelines of 5 CFR1320.5
A.8. Comments in Response to Federal Register Notice and Efforts to Consult Outside the Agency
A.9. Explanation of any Payment or Gift to Respondents
A.10. Assurance of Confidentiality Provided to Respondents
A.11. Justification for Sensitive Questions
A.12. Estimates of Annualized Burden Hours and Costs
A.13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers
A.14. Annualized Cost to Federal Government
A.15. Explanation for Program Changes or Adjustments
A.16. Plans for Tabulation and Publication and Project Time Schedule
A.17. Reason(s) Display of OMB Expiration Date is Inappropriate
A.18. Exceptions to Certification for Paperwork Reduction Act

References

Attachments

Attachment #1	Authorizing Legislation
Attachment #2a	Federal Register Notice
Attachment #2b	Summary of Public Comments and CDC Response
Attachment #3a	State Medicaid Tobacco Dependence Treatment Survey
Attachment #3b	Summary of Proposed Changes to the Survey
Attachment #4	Cover Email for Survey
Attachment #5	Thank You Email for Survey
Attachment #6	Cover Email for Feedback Report and Contact Person Verification

Abstract:

CDC previously received OMB approval to conduct the State Medicaid Tobacco Coverage Survey which describes state-based coverage plans for tobacco dependence treatments (OMB No. 0920-0691, exp. 8/31/2008). CDC is requesting OMB approval to reinstate information collection for an additional three years with minor changes. The new and revised questions will collect information about the recommendations made in the updated PHS clinical practice guideline issued in May of 2008 regarding coverage for combination therapies, smokeless tobacco use, and their familiarity with and use of the 2000 and 2008 PHS guidelines. Changes to the survey are detailed in Attachment 3b and are not expected to change the previous burden estimate. This reinstatement request also serves as a Privacy Impact Assessment.

Section A. Justification

A.1.*Circumstances Making the Collection of Information Necessary*

Tobacco is the leading cause of death and disability in the United States. While the Healthy People 2010 target for tobacco use is 12% in the adult population, the actual smoking prevalence in the U.S is 20.8%. The smoking prevalence in the Medicaid population averages 36%. The substantial gap between smoking prevalence in the Medicaid population and the Healthy People 2010 goals presents an important challenge to the health community at large and the Medicaid covered community in particular. Tobacco related disease causes considerable expense for state Medicaid programs. In fact, in 2000 tobacco use resulted in $75 billion in excess health care expenditures (MMWR, 2002). Because Medicaid serves large, low income populations, State Medicaid programs are in a position to play a key role in increasing cessation of tobacco use by providing and monitoring coverage for tobacco dependence treatment.

The Centers for Disease Control and Prevention is requesting approval from the Office of Management and Budget to collect information from State Medicaid programs to determine coverage for tobacco dependence treatment (medications and counseling), along with information about the utilization of the Public Health Service Guideline, *Treating Tobacco Use and Dependence* in developing and implementing their coverage. At present there are only a handful of states that provide comprehensive tobacco control coverage under Medicaid. The proposed survey is part of an ongoing process to determine Medicaid coverage for tobacco dependence treatment. The amount and type of coverage for tobacco-dependence treatment offered by Medicaid has been collected during 1998, 2000, 2001, 2002, 2003, 2005, 2006, and 2007. Surveys have been funded by the Robert Wood Johnson Foundation (RWJF) (1998, 2000-2003) and the Centers for Disease Control and Prevention (CDC) (2005-2007) (OMB No. 0920-0691, expiration date 8/31/2008).

As of 2006, 39 states covered some form of medication and 11 covered counseling. One of the national health objectives for 2010 is to increase insurance coverage of evidence-based treatment for nicotine dependence (i.e., total coverage of behavioral therapies and Food and Drug Administration [FDA] -approved pharmacotherapies) in Medicaid programs from 36 states to all states and the District of Columbia. Only two states (Oregon and Maine) have comprehensive

coverage (MMWR 2004). The proposed State Medicaid survey helps to track existing coverage and could improve the reach of tobacco control efforts and improve coverage for an important low income target population with high tobacco use rates. Having the proposed Medicaid coverage data provides evidence to states with less comprehensive coverage that coverage can be made available.

The Centers for Disease Control and Prevention (CDC), under Section 301 of the Public Health Service Act, (42 U. S. Code 241) (Attachment 1), is authorized to collect and make available through publications and other appropriate means, information on research relating to "causes, diagnosis, treatment, control and prevention of physical and mental diseases and impairment of man." In accordance with this authorization and in response to the high smoking prevalence in populations served by Medicaid and across the U.S., the Centers for Disease Control and Prevention proposes to conduct a survey to evaluate the coverage for tobacco dependence treatment provided by each state and the District of Columbia.

Privacy Impact Assessment Information

This is publically available policy information. Respondents are State Medicaid programs. The only individually identifiable information collected is the name and contact information of the person completing the survey and they are acting in their official capacity as a State Medicaid employee. This is collected so that the contractor can pose additional questions if necessary.

Overview of the Data Collection System

The data collection involves state Medicaid coverage for tobacco-use treatment information. Data will be collected electronically from each state Medicaid Program. The completed survey from the previous year is sent to the state person who completed the survey. They are asked to determine whether any changes have occurred in their state Medicaid tobacco treatment coverage since the previous year and up-date the information in the survey accordingly. This is then returned to the University of California Berkeley, Center for Health and Policy Studies. The data is public information but access is password protected.

Items of Information to be Collected

The attached survey details the items of information to be collected (Attachment 3a). These are primarily related to tobacco-use treatment medications and counseling coverage provided for Medicaid enrollees in the state. Data are also collected on when the coverage was initiated and what information the program collects to determine the efficacy of implementation. In addition, new and revised questions will collect information about the recommendations made in the updated PHS clinical practice guideline issued in May of 2008 regarding coverage for combination therapies, smokeless tobacco use, and their familiarity with and use of the 2000 and 2008 PHS guidelines (see Attachment 3b).

Identification of Website(s) and Website Content Directed at Children under 13 Years of Age

This information is posted on the CDC, Office on Smoking and Health website in the form of an MMWR. The website is accessible to the general public.

A.2.*Purpose and Use of Information Collection*

To increase both the use of treatment by smokers attempting to quit and the number of smokers who quit successfully, the Guide to Community Preventive Services recommends reducing the out-of-pocket cost of effective tobacco-dependence treatments (i.e., individual, group and telephone counseling and FDA-approved pharmacotherapies). The 2000 Public Health Service (PHS) Clinical Practice Guideline supports expanded insurance coverage for tobacco-dependence treatment. In 2000 approximately 32 million low-income persons in the United States received their health insurance coverage through the federal-state Medicaid program; 11.5 million (36%) of these persons smoked. CDC's purpose for funding this survey will be to continue to maintain the ability to measure progress toward reaching the Healthy People 2010 goals. The proposed project will continue this survey from 2008-2010.

This survey has been conducted on a number of occasions and has been demonstrated to be a credible source of information. It has been used as a basis of four MMWR reports (see References 1-4) and has been able to track progress toward the Healthy People 2010 goal regarding Medicaid Coverage of tobacco dependence treatment.

The numbers of states identifying coverage in each category (e.g. medication and counseling coverage under Medicaid) provides CDC with an opportunity to work with states with less comprehensive coverage to raise coverage levels. Without this data, CDC will not be able to measure progress toward the Healthy People 2010 goal of providing comprehensive tobacco dependence treatment under Medicaid.

The specific aims of the project are to:

- Conduct a study of all 50 states and the District of Columbia Medicaid Programs to determine coverage for tobacco dependence treatment (counseling and FDA-approved pharmacotherapies), and assess compliance with the PHS recommendations.
- Analyze and publish the data.

The project will provide an opportunity to assess the extent of coverage for tobacco dependence treatment under Medicaid. In 2002 although 36 states provided coverage for some FDA approved medications, only 10 provided some form of coverage for counseling and only 2 states provided comprehensive coverage, counseling and medication. Fifteen states provided no coverage.

Because Medicaid recipients have approximately 50% greater smoking prevalence than the overall U.S. adult population, they are disproportionately affected by tobacco-related disease and disability. Substantial action to improve coverage will be needed if the United States is to achieve the national 2010 health objective of 12% smoking prevalence among adults.

Privacy Impact Assessment Information

This is publically available policy information. Respondents are State Medicaid programs. The only individually identifiable information collected is the name and contact information of the person completing the survey and they are acting in their official capacity as a State Medicaid employee. This is collected so that the contractor can pose additional questions if necessary.

A.3. ***Use of Improved Information Technology and Burden Reduction***
Fifty-one responses (100%) are anticipated based on previous surveys. All surveys are submitted electronically via a web-based survey instrument. Respondents are given the opportunity to review previously submitted data, if it is unchanged, no additional information is required.

The Center for Health and Public Policy Studies, the contractor conducting the data collection on behalf of CDC, will employ appropriate security measures including protection of any physical media containing sample information, computer and network security to protect electronic content.

A.4. ***Efforts to Identify Duplication and Use of Similar Information***
This survey has been conducted in several previous years and no duplication of effort has been located. The American Lung Association conducts some independent analysis of state-level policies but does not collect standardized information in a format comparable to CDC's State Medicaid Survey. Very little has been published in the literature on Medicaid coverage for tobacco dependence treatment except by Helen Halpin, (formerly Schauffler) who will be conducting this survey. CMS was contacted when the initial OMB package was submitted and they were not conducting any similar data collection, nor was any planned for the future.

The existing data only address Medicaid coverage through 2007 and the proposed survey will collect data in 2009-11. Annual data collection has been important to demonstrate change and show progress toward the Healthy People 2010 objective.

A.5. ***Impact on Small Business or Other Small Entities***
No small businesses or small entities will be involved in this survey.

A.6. ***Consequences of Collecting Information Less Frequently***
Annual data collection has been important to demonstrate change and show progress toward the Healthy People 2010 objective. It also assists in moving the field forward as State Tobacco Control Programs and Medicaid Directors see the change and begin to understand the importance of subsequent coverage expansion in their state.

If information were collected less frequently, there would be reduced opportunity to support the movement toward broader coverage under Medicaid. Ongoing contact with the states also provides continuity with staff that has completed the document and there are fewer new people having to complete the survey annually. There are no legal obstacles to reducing the burden.

A.7. ***Special Circumstances Relating to the Guidelines of 5 CRF 1320.5***
This project fully complies with all guidelines of CFR 1320.5

A.8. ***Comments in Response to Federal Register Notice and Efforts to Consult Outside the Agency***

A.8.a. A notice was published in the Federal Register on September 25, 2008 (Vol. 73, No. 187, pp. 55515-55516) (See Attachment #2a). Two public comments were received, which included one request for copies of the data collection instruments and plans, and one letter of support. A summary of the comments and CDC's responses is provided in Attachment #2b.

A.8.b. Data will be collected annually by:
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Center for Health and Public Policy Studies
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510-643-1675

Centers for Disease Control and Prevention scientific consultants included:

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A.9. ***Explanation of any Payment or Gift to Respondents***
No payments or gifts are provided to respondents.

A.10. ***Assurance of Confidentiality Provided to Respondents***
This data collection concerns publicly available policy information. Respondents are State Medicaid programs. The only individually identifiable information collected is the name and contact information of the person completing the survey who is acting in his or her official capacity as a State Medicaid employee. This is collected so that the contractor can pose additional questions if necessary.

A. Privacy Act Determination
The CDC Privacy Act Officer has reviewed this application and has determined that the Privacy Act is not applicable. State Medicaid personnel complete the survey. The names of respondents who will address aspects of the various tobacco dependence treatment elements will be retained so that they can be contacted for clarification of responses, but these individuals will be speaking in their roles as individuals knowledgeable of these programs, and will not be providing any personal information about themselves other than their contact information as sources of information about the state Medicaid programs.

B. Safeguards
The CDC contractor, the Center for Health & Public Policy Studies (University of California, Berkeley) will safeguard the responses and will release information only with the written

approval of the CDC Project Officer. The Office for the Protection of Human Subjects at UC Berkeley has determined that this study does not constitute research involving human subjects and that IRB approval is not required.

C. Consent
No consent is required for this data collection as it is public information about State-level policies.

D. Voluntary
The State-level response to the data collection is voluntary.

A.11. ***Justification for Sensitive Questions***
This information collection does not involve personal or sensitive questions.

A.12. ***Estimates of Annualized Burden Hours and Costs***

A.12.a Estimated Burden to Respondents

Information collection is conducted electronically using the web-based "State Medicaid Tobacco Dependence Treatment Survey" (**Attachment 3a**). The most recently approved survey contained 42 questions and a request for each state to submit a written copy of their Medicaid coverage policies to study staff. Proposed changes for the next cycle of data collection are summarized in **Attachment 3b**. A few questions are no longer needed and will be deleted. The revised survey will include a few new questions that are needed to capture information about the 2008 PHS guidelines, and will also incorporate minor wording and question-order changes which reflect the research team's experience with previous cycles of information collection. The proposed changes are not expected to change the overall burden estimate. To minimize burden, each respondent's survey is pre-loaded with the previous year's data so that respondents only need to enter items that have changed since the previous submission. Depending on the number of changes (including follow-up and clarifications), burden to respondents may range from 15 minutes to one hour, with an estimated average of 30 minutes. Each respondent receives a cover email (**Attachment 4**) that includes a link to the web-based survey application, general instructions for completing the survey, and tailored comments that highlight survey items which require the respondent's attention. If responses are not received, study staff will telephone the designated contact person for follow-up. All 50 states plus the District of Columbia have reported in the past, and each responding state receives a thank-you email for its participation (**Attachment 5**). The total estimated burden hours are 26.

Prior to distributing the survey, study staff distribute a cover email that provides each state with a customized feedback report to show how its previous year's data compare to national averages for all states, and asks the recipient to confirm that he/she will continue to serve as the designated contact person for the upcoming survey (**Attachment 6**).

Table A.12-1. Estimated Annualized Burden Hours

Respondents	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
State Medicaid Programs	51	1	0.5	26

A.12.b Estimated Annualized Cost to Respondents

The survey is generally completed by an administrative-level manager designated by the state Medicaid director. The average hourly wage is estimated at $32.89 per hour (http://www.bls.gov). The total estimated annualized cost of the respondents' time is $839.

Respondents	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Average Hourly Wage	Total Cost
State Medicaid Program Administrative Manager	51	1	0.5	$32.89	$839

A.13. ***Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers***

There are no costs to respondents for capital equipment or record-keeping.

A.14. ***Annualized Cost to the Federal Government***

The total annualized cost of the survey is $72,500. The total includes 2.5% of a GS-13 level Federal employee who oversees the project in the role of project officer. The total also includes $70,000 per year for costs incurred by the University of California Berkeley, Center for Health and Public Policy Studies, which received an award to collect and analyze the data from the CDC Prevention Research Center. The tasks to be conducted by UC/Berkeley include:

-Development of Survey Questions
-Fielding survey by contractor
- Management of data files
- Format and distribution of pre-notification survey to state Medicaid Directors

- Format and distribution of survey
- Conduct follow-up with non-respondents to survey
- Data entry and preparation of final data set
- Creation of data file layout with defined labels and values to accompany final data set.

- Analysis of survey data by contractor: Perform analysis of survey data and prepare Final Report of analysis

A.15.*Explanation for Program Changes or Adjustments*
This is a request for reinstatement of a previously approved data collection. Minor changes will be incorporated into the survey but they are not expected to change the previously approved burden estimate.

A.16. *Plans for Tabulation and Publication and Project Time Schedule*
Data collection will be conducted annually, generally in the fall. Data collection will require 3 months. Data cleaning and analysis will also require approximately 3 months.

Data Analysis plan

Previous survey results are available and will be sent to respondents. An SPSS dataset for analysis will be prepared from the responses collected through the web-based survey tool.

Frequencies are tabulated for all questions. In addition, an Excel spread sheet is generated identifying specific coverage by Medicaid program and changes from the previous year are noted.

No statistical analysis is performed, as the data are not a statistical sample, rather they comprise the universe of Medicaid programs.

A.17. *Reason(s) Display of OMB Expiration Date is* Inappropriate
OMB number and expiration date will be displayed.

A.18. *Exceptions to Certification for Paperwork Reduction Act Submissions*
No exceptions are being requested.

References

1. CDC. State Medicaid Coverage for Tobacco-Dependence Treatments – United States, 1998 and 2000. MMWR 2002;50:979-82.

2. CDC. State Medicaid Coverage for Tobacco-Dependence Treatments – Unites States, 1994-2001. MMWR 2003;52:496-500.

3. CDC. State Medicaid Coverage for Tobacco-Dependence Treatments – United States 1994-2002. MMWR 2004;53:54-57.

4. CDC. State Medicaid Coverage for Tobacco-Dependence Treatments --- United States, 2006. MMWR 2008;57(05):117-122.