Each of the consent agreements announced today includes injunctive relief provisions requiring the settling parties to satisfy a standard of ''competent and reliable scientific evidence'' before again making the claims at issue. Each consent agreement further defines ''competent and reliable scientific evidence'' as requiring, among other things, two adequate and well-controlled human clinical studies (randomized controlled trials or RCTs) of the product. I encourage the Commission to explore more fully whether the articulation and scope of injunctive relief in these and similar settlements strikes the right balance between deterring deceptive advertising and preserving for consumers the benefits of truthful claims. The optimal amount and type of evidence to substantiate a future claim will vary from case to case. Similarly, a fact-specific inquiry may justify specially crafted injunctive relief in certain cases, such as bans, performance bonds or document retention requirements for underlying study data. I look forward to working with my fellow Commissioners to continue to examine and evaluate our formulation of the competent and reliable scientific evidence standard, as well as the ancillary injunctive provisions in consent agreements, in order to best protect consumers from the costs imposed upon them by deceptive advertising while encouraging competition and truthful advertising that benefits consumers.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–14–0916]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639–7570 or send an email to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Evaluation of Core Violence and Injury Prevention Program (Core VIPP)—Revision—(0920–0916, Expiration 1/13/2014)—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Injuries and their consequences, including unintentional and violence-related injuries, are the leading cause of death for the first four decades of life, regardless of gender, race, or socioeconomic status. More than 179,000 individuals in the United States die each year as a result of unintentional injuries and violence, more than 29 million others suffer non-fatal injuries and over one-third of all emergency department (ED) visits each year are due to injuries.[1] In 2000, injuries and violence ultimately cost the United States $406 billion, with over $80 billion in medical costs and the remainder lost in productivity.[1] Most events that result in injury and/or death from injury could be prevented if evidence-based public health strategies, practices, and policies were used throughout the nation.

CDC's National Center for Injury Prevention and Control (NCIPC) is committed to working with their partners to promote actions that reduce injuries, violence, and disabilities by providing leadership in identifying priorities, promoting tools, and monitoring effectiveness of injury and violence prevention, and to promote effective strategies for the prevention of injury and violence and their consequences. One tool NCIPC will use to accomplish this goal is through the use of the Core Violence and Injury Prevention Program (Core VIPP). This program funds state health departments (SHDs) to build their capacity to disseminate, implement, and evaluate evidence-based/best practice programs and policies. This evaluation will consider the implementation and outcomes of Core VIPP during the five-year funding period from August 2011 to July 2016. The Core VIPP will support funded states in building capacity and achieving health impact in their states. The key components of violence and injury prevention (VIP) capacity for Core Base Integration Component (BIC) VIPP are defined as: infrastructure, evaluation, strategies, collaboration, and surveillance.

CDC requests OMB approval to continue to collect program evaluation data for Core VIPP for an additional three-year period. The purpose of the evaluation is to track states' progress toward: (1) Achieving the Performance Measures identified in the Funding Opportunity Announcement (FOA); (2) building and/or sustaining their VIP capacity; and (3) achieving their focus area SMART (Specific, Measurable, Attainable, Reasonable, and Time-bound) objectives. The ability of states to make progress towards their SMART objectives will serve as a measure of Core VIPP's impact on the burden of violence and injury related morbidity and mortality in funded states.

The primary data collections methods will be used in the evaluation include: (1) Interim and annual progress reports, (2) online surveys, and (3) interviews. The progress reports will track states' performance measures and the activities stated in the Core VIPP FOA and monitor states' progress toward their focus area SMART objectives; the online survey will be used to measure grantees' changes in VIP capacity. Interviews will be used to provide more in-depth information about the key facilitators and barriers states have encountered while implementing their violence prevention programs.

The table below details the annualized number of respondents, the average response burden per interview, and the total response burden for the surveys and telephone interviews. Estimates of burden for the survey are based on previous experience with evaluation data collections conducted by the evaluation staff. The State of the States (SOTS) web-based survey assessment will be completed by 20 Core Funded State Health Departments (SHDs) and will take 3 hours to complete. The SOTS Financial Module will also be completed by the 20 BIC funded SHD and will take 1 hour to complete. The supplemental SOTS Survey Questions will be completed by 20 BIC funded SHDs and take 1.5 hours to complete. The BIC telephone interviews will take 1.5 hours and will be completed by the 20 Core funded SHDs.

relevant to the benefits and costs of substantiating a particular claim. These factors include: the type of claim, the product, the consequences of a false claim, the benefits of a truthful claim, the cost of developing substantiation for the claim, and the amount of substantiation experts in the field believe is reasonable.'' FTC Policy Statement Regarding Advertising Substantiation, appended to *Thompson Medical Co.,* 104 F.T.C. 648, 839 (1984), *aff'd,* 791 F.2d 189 (D.C. Cir. 1986), *cert. denied,* 479 U.S. 1086 (1987). Formulating the required level of substantiation for injunctive relief should necessarily be grounded in the factors set forth in this policy statement, although additional considerations might also be relevant.

[1] Finkelstein EA, Corso PS, Miller TR, Associates. *Incidence and Economic Burden of Injuries in the United States.* New York: Oxford University Press; 2006.

The Regional Network Leader (RNL) surveys will be completed by the 5 RNL funded SHDs and will take 1 hour to complete a telephone interview. The four Surveillance Quality Improvement (SQI) funded SHDs will complete a one-hour telephone interview. The four Motor Vehicle Child Injury Prevention Policy (MVP) SHDs will complete a telephone interview that will take one hour to complete.

There are no costs to respondents other than their time. The total estimated annual burden hours are 163.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
Core VIPP Funded SHD Injury Program director.	State of the States Survey (SOTS)—Attachment C.	20	1	3
Core VIPP Funded SHD Injury Program director.	SOTS Financial Module—Attachment E	20	1	1
Core VIPP Funded SHD Injury Program management and staff.	Supplemental SOTS Survey Questions—Attachment F.	20	1	1.5
Core VIPP Funded SHD Injury Program management and staff.	BIC Telephone Interview—Attachment D	20	1	1.5
RNL awardees	RNL Telephone Interview—Attachment G	5	1	1
RNL awardees	RNL Network Satisfaction Survey—Attachment H.	5	1	1
RNL awardees	RNL Needs Assessment Survey—Attachment I.	5	1	1
SQI awardees	SQI Telephone Interview—Attachment J	4	1	1
MVP awardees	MVP Telephone Interview—Attachment K	4	1	1

LeRoy Richardson,

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day–14–0941]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–7570 or send comments to LeRoy Richardson, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Evaluation of Dating Matters: Strategies to Promote Healthy Teen Relationships ™ (0920–0941, Expiration 5/31/2016)—Revision—National Center for Injury Prevention and Control (NCIPC)—Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Dating Matters: Strategies to Promote Healthy Teen Relationships ™ is the Centers for Disease Control and Prevention's new teen dating violence prevention initiative.

To address the gaps in research and practice, CDC has developed *Dating Matters,* teen dating violence prevention program that includes programming for students, parents, educators, as well as policy development. Dating Matters is based on the current evidence about what works in prevention and focuses on high-risk, urban communities where participants include: Middle school students age 11 to 14 years; middle school parents; brand ambassadors; educators; school leadership; program implementers; community representatives; and local health department representatives in the following communities: Alameda County, California; Baltimore, Maryland; Broward County, Florida; and Chicago, Illinois. In the evaluation, a standard model of TDV prevention (Safe Dates administered in 8th grade) will be compared to a comprehensive model (programs administered in 6th, 7th, and 8th grade as well as parent, educator, policy, and communications interventions).

The primary goal of the current proposal is to amend the available administration formats for the student follow-up survey for the participating youth as they matriculate into high school and to propose the use of monetary gifts for the completion of the student follow-up survey by high school youth to the approved outcome and implementation evaluation of Dating Matters in the four metropolitan cities to determine its feasibility, cost, and effectiveness. Following Dating Matters program participants into high school may prove challenging and without a high response rate, the evaluation design may be compromised. To address such concerns, we are requesting to provide a nominal monetary gift to participants in an amount up to $25. The use of this monetary gift is critical to maintain a high response rate of this high-risk and highly mobile sample. Response rates for the follow-up survey were anticipated to be 90%, however, in