

**A Pilot Project to Evaluate the Use of Exposure Control Plans for Bloodborne Pathogens  
In Private Dental Practices**

Request for Office of Management and Budget (OMB) Review and Approval  
for a Federally Sponsored Data Collection

Section A

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July 15, 2013

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## **A. Justification**

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

#### Background

This is a new information collection request from the National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, seeking data collection approval for a one year pilot project. The proposed information collection will evaluate the extent to which exposure control plans mandated by the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens (BBP) Standard (29CFR 1910.1030) are implemented in private dental offices an important segment of the non-hospital based healthcare system.

The Centers for Disease Control and Prevention (CDC) estimate that healthcare workers sustain nearly 600,000 percutaneous injuries annually involving contaminated sharps. In response to both the continued concern over such exposures and the technological developments which can increase employee protection, Congress passed the Needlestick Safety and Prevention Act directing OSHA to revise the BBP standard to establish requirements that employers identify and make use of effective and safer medical devices. That revision was published on Jan. 18, 2001 and became effective April 18, 2001.<sup>1</sup>

The revision to OSHA's BBP standard added new requirements for employers, including additions to the exposure control plan and maintenance of a sharps injury log.

OSHA has determined that compliance with these standards significantly reduces the risk that workers will contract a bloodborne disease in the course of their work.<sup>2</sup> However, bloodborne pathogens programs, policies, and standards for healthcare workers are based primarily on hospital data.

Approximately one-half of the 14 million healthcare workers in the United States are employed in non-hospital-based settings, such as physician offices, home healthcare agencies, correctional facilities, or dental offices and clinics. Little information is known about the risk management practices in these non-hospital settings.<sup>3</sup>

A small study conducted by NIOSH<sup>4</sup> found that although seven of the eight correctional healthcare facilities visited had written exposure control plans, only two were reviewed and updated annually as required by the OSHA BBP Standard. One reason postulated for non-compliance was that hospital-based standards, policies, and programs may not be appropriate to non-hospital settings. It is important to identify effective methods for using exposure control plans in non-hospital settings and to verify whether the specificity and relevance of BBP training and educational materials for non-hospital facilities can positively impact compliance in dental settings.

NIOSH's mission since its creation by the Occupational Safety and Health Act [29CFR § 671] of 1970 (Attachment A) is to provide national and world leadership to prevent workplace illnesses and injuries.

In order to address occupational safety and health issues of the nation, NIOSH organized its National Occupational Research Agenda (NORA) program portfolio into ten industrial sectors as defined by the North American Industry Classification System (NAICS). Each sector has a sector council (comprised of representatives from industry, labor, academia and NIOSH), which is responsible for identifying important occupational health and safety issues and occupational safety and health goals for their respective industry sectors. The Healthcare and Social Assistance (HCSA) Sector Council has identified important knowledge gaps and research needs in their report *State of the sector/healthcare and social assistance: identification of research opportunities for the next decade of NORA*.<sup>5</sup> Among the priority action items to eliminate sharps injuries and their impacts include improved surveillance, education and training of HCSA workers, identification of human and organizational factors that reduce adherence to safe practices and developing interventions to address them.

The proposed data collection will also meet goals identified by the HCSA Sector Council<sup>6</sup> including:

**Intermediate Goal 4.6** Advocate for the establishment, annual update and implementation of a comprehensive exposure control plan that complies with the OSHA BBP Standard or relevant state standard, and CDC guidelines as appropriate in all healthcare settings. Little information is known about the risk management practices in non-hospital settings including dental facilities.

**Activity/Output Goal 4.6.1:** Identify the types of healthcare establishments most likely to not write, update, or implement a written exposure control plan, and the reasons for not doing so.

**Activity/Output Goal 4.6.2:** Partner with relevant professional organizations, associations, and unions in encouraging all healthcare establishments to write, update, and implement exposure control plans.

**Activity/Output Goal 4.6.4:** Develop materials, tools and examples to assist workplaces to develop and implement comprehensive exposure control plans.

Information will be gathered to determine the number of private dental practices with existing exposure control plans, the number of exposure control plans or other resources actively being used to prevent occupational exposures to bloodborne pathogens, and types of barriers to actively using an exposure control plan to prevent such exposures.

The proposed survey will only be available on-line. Dentists in private practice will be selected from a commercially available email distribution list compiled by Aegis Communications representing about 30% of all private practice dentists in the U.S.

### **1.1 Privacy Impact Assessment**

No information in identifiable form (IIF) will be collected during the survey. The federal government approved version of SurveyMonkey<sup>7</sup> (a commercially available web-based survey software application) will be used by our partner (Organization for Safety, Asepsis and

Prevention, OSAP) to collect information on private dental practices. The hyperlink and internet address to the survey will only be made available by email to dentists on a double-opt-in email distribution list of dentists, hence the information will not be directed at children under the age of thirteen years. Only aggregated survey results will be made available to the public.

Please see below for additional information related to the Privacy Impact Assessment.

The federal government approved version of SurveyMonkey will be used to collect and manage the data. Aegis Communications, a publishing partner of OSAP, will send an invitation by email to dentists on their double-opt-in distribution list. The email will contain a link to the survey. The survey will be accessible 24/7 during the 4 week data collection period. The survey will take respondents about 15 minutes to complete. Screen shots of the survey are provided in Attachment K. \_

All data collection will be conducted by our partner OSAP. At the conclusion of the survey, the data will be stored in a secure manner at OSAP headquarters in Annapolis, MD and subsequently transferred to NIOSH where it will be stored in a secure manner.

All data collection activities will be conducted in full compliance with the CDC regulations to maintain the privacy of data obtained on persons and to protect the rights and welfare of human subjects, as contained in Title 28 of the Code of Federal Regulations, Parts 22 and 46.

No individually identifiable information is being collected. All information to be collected pertains to facility management practices and does not involve any information about an individual. Examples of types of management practices to be collected include: presence of and extent of use of existing exposure control plans; whether the plan or other resources are actively used to prevent occupational exposures; available resources and barriers to use such as relevant education materials, knowledge, costs and availability; and descriptive information on the type, size and geographic location of the dental practice. Information collected will be used to develop strategies to overcome key barriers to compliance, to guide health and safety promotion, interventions, and future research.

No information will be directed at children under the age of thirteen years.

The proposed research will involve the collection of information utilizing a federal government approved version of SurveyMonkey. The link to the survey will only be distributed to dentists who are on the Aegis email distribution list.

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

The purpose of this project is to develop and conduct a one-time survey that provides current, baseline information on the extent to which BBP exposure control plans are being used in private dental offices. Currently BBP programs, policies, and standards for healthcare workers are based primarily on hospital data. It is anticipated that information acquired during this pilot study will be applicable to other non-hospital healthcare settings. This information is not available elsewhere and will be used to develop strategies to overcome key barriers to compliance, and to guide health and safety promotion and prioritize future research. Without this data, NIOSH will

not have any information on the extent to which private dental practices are using exposure control plans to protect dental practitioners from exposure to bloodborne pathogens and other potentially infectious materials.

This project has been funded by NIOSH as part of the National Occupational Research Agenda (NORA).

NIOSH is collaborating with OSAP to perform this work. As a non-profit partner, OSAP is a unique group of dental educators and consultants, researchers, clinicians, industry representatives, and other interested persons with a collective mission to be the world's leading advocate for the safe and infection-free delivery of oral healthcare. OSAP supports this commitment to dental workers and the public through quality education and information dissemination. OSAP's unique membership includes the variety of partners critical to evaluate use of the OSHA BBP standard, identify barriers and develop strategies to overcome barriers to compliance. OSAP's publishing partner, Aegis Communication, will develop a sampling frame consisting of email addresses of private general practice dentists and dentist specialists. Aegis will send an invitation by email to dentists on their distribution list asking them to participate in the voluntary survey; the email will include a hyperlink to the survey website.

### **2.1 Privacy Impact Assessment Information**

At the conclusion of the data collection, a report summarizing aggregated survey data will be disseminated via a peer-reviewed journal where it will be available to dental practitioners and other interested parties. The survey results will help dental practitioners and public health researchers better understand barriers to implementing exposure control plans and intervention strategies. The proposed data collection will have minimal impact of respondent's privacy since no individually identifiable information will be collected.

## **3. Use of Improved Information Technology and Burden Reduction**

In order to maximize efficiency and reduce burden, a web-based survey is proposed for all data collection (100% of responses). At a secure web site, the survey will be constructed for easy respondent use, allowing the automatic administration of skip patterns, while maintaining a simple, seamless navigation. Web-based surveys have gained increasing acceptance as a research tool as they offer many advantages, including:

- On-line surveys create cost efficiencies because respondents complete them during a much shorter window of time than other survey modes, and at a substantially reduced cost (i.e., less labor is involved than telephone or in-person surveys; postage is required for mail-based surveys);
- On-line surveys create time efficiencies (i.e., less time to complete the survey because it can be programmed to efficiently guide respondents through skip patterns so that they are not asked questions that do not apply to them or have to spend time navigating through complex instructions);
- All responses are automatically recorded, allowing for minimal data cleaning, and rapid

tabulation and analysis of findings;

- Respondents potentially have the option of answering questions in a private setting where they feel comfortable and at ease (e.g., at home);
- Respondents can complete the survey within their own time schedule;
- Previous research<sup>8</sup> suggests that healthcare workers prefer completing an online survey when given a choice between a web survey and a paper survey.

#### **4. Efforts to Identify Duplication and Use of Similar Information**

NIOSH has searched the scientific literature, contacted colleagues at NIOSH and OSHA, contacted professional organizations representing dentists, and examined questions available in previous surveys of dentists. There are no similar data available.

#### **5. Impact on Small Businesses or Other Small Entities**

Because dentists will comprise the sampling pool for this survey and more than 97% of all private dental offices are small businesses (i.e., less than 20 employees as defined by OSHA), issues encountered in small businesses will be covered in this study. Participation is completely voluntary, and respondents will be encouraged to complete the survey on their own time. All respondents will be instructed to complete the entire survey, and questions have been held to the minimum required for the intended use of the data.

#### **6. Consequences of Information Collected Less Frequently**

This request is for a one-time data collection. If this data collection does not take place, NIOSH or others will not possess information on current usage of exposure control plans to guide interventions and future research for this important sector of the economy. There are no legal obstacles to reduce the burden.

#### **7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

This request fully complies with the regulation 5 CFR 1320.5.

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

A. A 60-day Federal Register Notice was published in the *Federal Register* on February 12, 2013, Vol. 78, No. 29, pages 9921-9922 (Attachment B). One non-substantive comment was received from the public and a response was sent (Attachment J).

B. NIOSH consulted with numerous individuals and organizations outside the agency regarding the usefulness of the proposed data collection. In addition, we have contracted with the

Organization for Safety, Asepsis and Prevention (OSAP) to provide guidance on the survey protocol, sampling design, and questionnaire development and testing.

In 2010, the project proposal from OSAP was peer-reviewed and competitively rated based on project approach, potential impact, innovation and significance. The project received favorable scores and was selected for funding by NIOSH.

In 2011, the survey instrument was developed and/or reviewed by the following dental practitioners, academicians, educators, and subject matter experts.

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## **9. Explanation of Any Payment or Gift to Respondents**

No payments will be offered to respondents as remuneration for their participation in this survey.

## **10. Assurance of Confidentiality Provided to Respondents**



This submission has been reviewed by NIOSH who determined that the Privacy Act does not apply. Risks to participants are low, since no information in identifiable form (IIF) will be collected. NIOSH and OSAP will only be reporting and publishing aggregated data from this survey.

### *IRB Approval*

The Chair of the NIOSH Human Subjects Review Board (HSRB) determined that the data collection activities for assessing compliance by dental practices with the OSHA BBP standard do not involve the collection of information about an individual, but rather that the data collection pertains only to facility management practices. Therefore, the proposed activity does not require review by the NIOSH HSRB. (Attachment D).

## **10.1 Privacy Impact Assessment Information**

- A. The CDC's Information Collection Review Office has reviewed this application and has determined that the Privacy Act is not applicable. No individually identifiable information will be collected. Survey invitees will be informed in the invitation letter that their participation in the survey is voluntary.
- B. Access to micro data will be limited to authorized NIOSH project staff. NIOSH facilities have 24 hour security, and all electronic data will be stored on secure servers accessible only with passwords. OSAP and any other NIOSH contractor will be required to follow equivalent procedures. Survey data will be electronically submitted to NIOSH using password protected encryption techniques.
- C. Respondents will be provided with information that will explain the intended use of the information collected, describe any risks participants may face, and inform them that their participation is completely voluntary. Consent is implied when respondent begins the survey.
- D. Respondents will be informed that their participation is voluntary, and that they may discontinue the survey at any time. The Privacy Act does not apply. No individually identifiable information is being collected.

## **11. Justification for Sensitive Questions**

The web-based data collection instrument will be self-administered and contain no IIF. Respondents will have complete anonymity in answering the questions; the questions are not of a sensitive nature as they pertain to facility management practices and not personal practices. Information on management health and safety practices may be viewed as sensitive; however, such information will be reported in aggregate form only (i.e., not linked to individual dental office). Information on use of the BBP exposure control plan will be used to guide health and safety promotion, interventions, and future research.

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

## A. Estimates of Annualized Burden Hours

OSAP is working with a publishing partner that has an email distribution list of 49,172 private practice dentists representing general dentists and specialists. This sampling frame represents nearly 30% of the total population of U.S. private practice dentists. The survey sample, totaling 40,575 dentists, will include general dentists, oral and maxillofacial surgeons, pediatric dentists and periodontists. Other dentist specialists including endodontists, oral pathologists, orthodontists, prosthodontists and public health dentists will not be included in the sample because they either do not work in private practice and/or were at relatively low risk of exposure to BBPs.

The targeted number of completed questionnaires is estimated at about 20,287 (50% participation rate). The survey is estimated to take about 15 minutes for respondents to complete. This survey completion scenario yields an annualized hour burden estimate of 5,072 hours (Table A12-1). No direct costs will accrue to respondents other than the time to complete the survey.

**Table A12-1. Estimates of Annualized Burden Hours**

<b>Respondents</b>	<b>Form Name</b>	<b>Number of Respondents</b>	<b>Number of Responses Per Respondent</b>	<b>Average Burden per Response (in hours)</b>	<b>Total burden (in hours)</b>
Private Dental Practices	BBP Exposure Control Plan Survey	20,287	1	15/60	5,072
<b>Total</b>					<b>5,072</b>

## B. Estimates of Annualized Burden Costs

The mean hourly wage rates for general dentists and dental specialists was based on data obtained from the Bureau of Labor Statistics, Occupational Employment and Wages, May 2011.<sup>9</sup> Mean hourly rates were unavailable for pediatric dentists and periodontists who are classified as , “dentists, all other specialists”. The wage rate for this occupational category was used for each of these specialists.

**Table A12-2. Estimates of Annualized Costs**

<b>Type of Respondent</b>	<b>Total Burden Hours</b>	<b>Hourly Wage Rate</b>	<b>Total Cost</b>
General Dentists	3966	77.76	\$308,396
Oral and Maxillofacial Surgeons	333	104.51	34,802
Pediatric dentists	508	80.77	41,031
Periodontists	265	80.77	21,404

<b>Total</b>	<b>5,072</b>		<b>\$405,633</b>
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### 13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no additional cost burdens for the respondents.

### 14. Annualized Cost to the Government

Total costs include work performed by OSAP, Aegis Communications, and CDC personnel. OSAP will be responsible for programming the web version of the survey, usability testing of the web survey, conducting the survey, data cleaning, and preparing a final report. Estimated annualized costs to the Federal Government for the survey period are presented in Table A14 below.

**Table A14. Estimated Annualized Cost to the Federal Government**

<b>Item</b>	<b>FY2012</b>	<b>FY2013</b>	<b>FY2014</b>	<b>Annualized Cost</b>
<b>CDC Personnel</b>	\$7,113	\$8,891	\$4,446	\$6,817
<b>Contractors</b>	\$25,000	\$25,000	\$0	\$16,667
<b>Supplies</b>	\$0	\$0	\$0	\$0
	<b>Total</b>			\$23,484

### 15. Explanation for Program Changes or Adjustments

This is a new data collection.

### 16. Plans for Tabulation and Publication and Project Time Schedule

OSAP was responsible for cognitive testing of the survey instrument, programming of the paper version of the survey instrument into SurveyMonkey, data cleaning and preparation of a report presenting aggregated survey findings. Tables and/or charts will be used to present frequency distributions of response categories to each question in the survey.

**Table A16. Project Time Schedule**

<b>Activity</b>	<b>Time Schedule (months after OMB approval)</b>
Programming of web survey	During OMB review
Survey pre-test	During OMB review
Data collection	1 month
Data cleaning	2 months
Data analysis	4 months
Survey report	6 month

### 17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is not inappropriate.

## **18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.