

Workplace Violence Prevention Programs in NJ Healthcare Facilities

**Request for Office of Management and Budget Review and
Approval for Federally Sponsored Data Collection**

Section A

Project officers: Marilyn Ridenour, BSN, MPH
Nurse Epidemiologist
Analysis and Field Evaluations Branch

Dan Hartley, Ed.D.
Epidemiologist
Analysis and Field Evaluations Branch

National Institute for Occupational Safety and Health
Division of Safety Research
1095 Willowdale Road, MS 1811
Morgantown, WV, 26505

Phone: 304-285-5879
Fax: 304-285-6235
E-mail: dvn7@cdc.gov

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A. Justification

A.1 Circumstances Making the Collection of Information Necessary

This is a revised Information Collection Request (ICR) from the National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention. The approved ICR (0920-0914) was for data collection at 50 hospitals (estimated annualized 17 burden hours) and for a 4000 nurse survey (estimated annualized 444 burden hours) which data collection is ongoing. Data collection is ongoing at the hospitals and for the nurse survey. We are revising our existing ICR to include 2 new respondents which are nursing homes and home healthcare aides. This revised ICR is for data collection at 20 nursing homes (estimated annualized 7 burden hours) and for a 4000 home healthcare aide survey (estimated annualized 444 hours). The burden table has also been corrected to include the annualized burden hours as the burden table in the previous ICR was not annualized. Under the Public Law 91-596 (Section 20[a][1]), the NIOSH is tasked with conducting research relating to occupational safety and health (Appendix A). One of NIOSH's goals is to reduce workplace homicides and violence to healthcare workers. In order to achieve this goal, NIOSH is conducting research on the prevention of workplace violence in the healthcare industry. The objective of the current project is to evaluate the impact of New Jersey Violence Prevention in Health Care Facilities Act. The need for this information collection is described in this section.

Healthcare workers are nearly five times more likely to be victims of violence than workers in all industries combined¹. While healthcare workers are not at particularly high risk for job-related homicide, nearly 60% of all nonfatal assaults occurring in private industry are experienced in healthcare. Six states have enacted laws to reduce violence against healthcare workers by requiring workplace violence prevention programs². However, little is understood about how effective these laws are in reducing violence against healthcare workers.

The workforce that provides nursing home healthcare is growing rapidly, with increases likely to continue with the aging population and changes in healthcare delivery policy. Nursing and residential care facilities reported 204,300 nonfatal injuries and illnesses in 2007 with a rate of 8.8 per 100 full-time workers which is the highest for the healthcare and social assistance sector.

There are limited studies on aggression and violence towards home care workers. Kendra (2006) found that 11.5% of home healthcare aides experience angry and abusive patients or families about half the time.

The long-term goal of the proposed project is to reduce violence against healthcare workers. The objective of the proposed study is two-fold: (1) to examine healthcare facility (hospitals and nursing homes) compliance with the New Jersey (NJ) Violence Prevention in Health Care Facilities Act, and (2) to evaluate the effectiveness of the regulations in this Act in reducing assault injuries to workers. Our central hypothesis is that facilities with high compliance with the regulations will have lower rates of employee violence-related injury. We formulated this hypothesis based on our preliminary NIOSH-funded work examining the effectiveness of a similar law in California using NJ hospitals as control sites. In this work, we found that assault rates to emergency department and psychiatric unit workers in California decreased following

enactment of the California law, compared to assault rates in NJ hospitals³. We also found that California hospitals had implemented many of the elements of a comprehensive violence prevention program^{4,5}. However, the California evaluation was unable to measure how the comprehensiveness of hospital workplace violence prevention programs changed as a result of the California law because we were unable to describe hospital programs prior to enactment of the law. The proposed project will address this limitation by using the data collected from New Jersey hospitals as the baseline measure of program comprehensiveness.

We will test our central hypothesis by accomplishing the following specific aims:

1. Compare the comprehensiveness of healthcare facility workplace violence prevention programs before and after enactment of the NJ regulations;

Working hypothesis: Based on our preliminary research, we hypothesize that enactment of the NJ regulations will improve the comprehensiveness of hospital and nursing home workplace violence prevention program policies, procedures and training.

2. Describe the workplace violence prevention training nurses and home healthcare aides receive following enactment of the NJ regulations;

Working hypothesis: Based on our preliminary research, we hypothesize that nurses and home healthcare aides will receive at least 80% of the workplace violence prevention training components mandated in the NJ regulations.

3. Examine patterns of assault injuries to workers before and after enactment of the regulations;

Working hypothesis: Based on our preliminary research, we hypothesize that rates of assault injuries to workers will decrease following enactment of the regulations.

Results from the proposed project will contribute to the development and dissemination of a NIOSH numbered document, a r2p output, that outlines the benefits of comprehensive healthcare workplace violence prevention plans, including organizational- and worker-level barriers and facilitators to implementation. Currently, six states have legislation in place to reduce violence to healthcare workers, and many others have considered implementing laws. Findings from the proposed project can ultimately be valuable to states considering introducing or amending similar workplace violence prevention legislation, to federal government agencies, and to international healthcare systems.

Privacy Impact Assessment

Overview of Data collection System

Phase I: Facility (hospital and nursing home) survey

Abstraction from Workplace Violence Prevention Policies and Procedures: These data will be used to measure the compliance of the facility's workplace violence prevention program. At the time of recruitment, Dr. Blando will request a copy of the facility's workplace violence prevention policies, procedures and training materials. Receipt of these documents will be

requested via email attachment. If not possible by email, we will provide a pre-paid, pre-addressed mailer to the facility for mailing the documents.

The instrument was developed and piloted by the research team and includes questions that follow the specific elements of the NJ regulations. Dr. Blando will abstract the information prior to the interviews with the violence prevention committee chair. A reliability check of the abstraction will be performed with an additional member of the research team. A copy of the abstraction form is included in Appendix D.

Interviews with Violence Prevention Committee Chairs: The purpose of these interviews is to supplement (and clarify, if needed) data abstracted from the policies, procedures and training materials, as well as to obtain qualitative information about the chair's knowledge and attitudes about the NJ regulations. The interviews will utilize a standardized questionnaire designed for administration to the Chair of the Workplace Violence Prevention Committee. At the time of recruitment, Dr. Blando will schedule an interview to be conducted at the facility with the committee chair.

This instrument was also developed and piloted by the California study research team. The interview protocol is primarily open-ended to allow for details about the facility's workplace violence prevention program that may not be documented in the written policies and procedures, as well as information about barriers and facilitators to implementing the regulations. Based on the pilot, we estimate that each interview will take approximately 45-60 minutes to complete.

Violent Event Incident Reports and Administrative Records: These data will be used to measure changes in the incidence rate of employee violence before and after enactment and phased implementation of the NJ regulations. The violent event data will also be used to describe the circumstances surrounding the events. According to the regulations, facilities are required to gather the following information after a violent incident: date, time and location of the incident; identity, job title and job task of the victim; identity of the perpetrator; description of the violent act, including whether a weapon was used; description of physical injuries; number of employees in the vicinity when the incident occurred, and their actions in response to the incident; recommendations of police advisors, employees or consultants; and actions taken by the facility in response to the incident.

In our pilot with 8 hospital facilities in the Fall 2010, violent event data were available electronically for all sites. For data available electronically, we will request a personal de-identified dataset that contains the variables required in the NJ regulations. For facilities where data are not available electronically, we will abstract on-site from hard-copy incident reports. Upon request from a facility, we will develop a standardized data use agreement to access violent event data. Dr. Blando will take primary responsibility for the abstraction from both on-site and electronic files. Ms. Emily O'Hagan R.N. (retired NJ Department of Health and Senior Services), who will work as a consultant on the proposed project, will assist Dr. Blando with data abstraction. Ms. O'Hagan was a key field staff member in the previous NIOSH-funded California legislation study. In addition, her experience in both clinical care and public health will have significant utility in this phase of the project. A reliability check of abstracted violent event data will be performed with an additional member of the research team. A copy of the employee incident information abstraction form is included in Appendix.

Violent event data will be requested for the three years preceding enactment of the legislation (2009-2011) and three years' post enactment (2012-2014). In keeping with the regulation's

definition of a violent event and to standardize data collection across facilities, we will request incident reports that document physical assaults only. Based on our preliminary research in hospitals, workers are more inclined to report physical violence than verbal threats of violence, which gives us a level of confidence that underreporting will be minimal.

The NJ Department of Health and Senior Services (NJDHSS) Division of Health Care Facility Evaluation and Licensing, Office of Health Care Financing maintains financial and operational data on all licensed health care facilities within the state. This information is collected via standard annual data submissions (i.e. Form C data) that healthcare facilities must complete in June as per N.J.A.C. 8:31B. This information is detailed and contains specifics such as employee hours, physician fees, and other cost information. Employee hour data will be used as the denominator values in incidence rate calculations to accomplish Specific Aim 3. The employee hours data are broken down by 50 different departmental cost centers, which include all employee hours for the emergency department, behavioral health, and skilled nursing care units. Therefore, the total number of employee hours charged to a particular cost center will be contained within this form C data if a licensed health care facility has an emergency department, behavioral health care unit, or skilled nursing care. Each of the eligible hospitals and nursing homes for the proposed study fit these criteria.

The study team had abstracted employee hours data for emergency departments and behavioral health units in the previous study for the years 1992 - 2001, at which time the data were maintained via hard copy. However, since 2001 the NJDHSS has maintained the data in electronic formats. These electronic databases are considered public information and can be obtained via Open Public Records Act (OPRA) requests. The study team has already obtained the Form C data for all hospitals in NJ for the years 2005 - 2009 through a previous OPRA request. Data becomes available approximately one year after the data submission. Therefore, 2010 data will become available in June 2011.

Phase II: Nurse survey and Home Healthcare Aide Survey

Self-Administered Survey: The purpose of this survey is to document the type and frequency of workplace violence prevention training nurses and home healthcare aides receive. The survey will be mailed with a self-addressed, stamped envelope for return to the third-party contractor. The contractor will track and manage the mailing and response. The contractor will also enter the survey data and send the completed de-identified tracking and survey databases to NIOSH.

The survey will include questions about nurses' knowledge and home healthcare aides' knowledge of the NJ regulations, whether they receive the training components mandated in the regulations and their experience with verbal and physical assaults in the previous year. We estimate the survey to take no more than 20 minutes to complete. A copy of the survey is included in Appendix G. The nurse survey was pilot-tested in Summer 2011 prior to full-scale administration. The home healthcare aide survey will be pilot-tested in the Fall 2012 prior to full-scale administration.

A letter of introduction with information on consent (see appendix) will be included with the survey questionnaire. Names of nurses and home healthcare aides will not be recorded on the survey questionnaire and thus, their questionnaires will not be shared with their employers. The

survey poses minimal risk to nurses and home healthcare aides and human subjects review approval is not a problem.

All hard-copy forms will be stored in locked filing cabinets in locked project staff offices and shredded once data entry and cleaning are completed.

Pilot Test

In preparation for the proposed project, we pilot-tested the data collection instrument to be used to interview administrators about the elements of their facility's workplace violence prevention programs. The pilot test was instrumental in improving the interview process and provided assurance that an interview will be an effective way of obtaining detailed information from administrators. The pilot test involved administration of the survey in a direct face-to-face interview at hospitals and nursing homes in an identical manner proposed for this project. The pilot was conducted with eight NJ healthcare facilities in October and November 2010. Facilities were selected to represent various hospital types, specifically acute care (general) and psychiatric hospitals, and sizes. Two nursing homes participated in the pilot test. Based on the pilot, we developed two data collection instruments, one as the interview form and the other to abstract data from the facility's written programs. To keep the interview to 45-60 minutes, the abstraction form was developed to obtain information on the facilities workplace violence prevention program, leaving the interview to provide more qualitative input into the barriers and facilitators to interpreting and implementing the NJ regulations.

Items of Information to be Collected

No individually identifiable information is being collected.

For the *Facility (Hospital and Nursing Home) Survey*, the following information will be collected: 1) establishment of a violence prevention committee with the required membership including at least 50% of the committee members to have routine patient contact, 2) a written violence prevention plan with the required components, 3) initial and annual violence training with required elements, 4) sufficiently trained personnel who can identify risk factors for violence and respond appropriately, 5) recordkeeping of all violent acts against employees while at work, and 6) a post-incident response system.

For the *Violent Event Incident Reports and Administrative Records*, according to the regulations, facilities are required to gather the following information after a violent incident: date, time and location of the incident; identity, job title and job task of the victim; identity of the perpetrator; description of the violent act, including whether a weapon was used; description of physical injuries; number of employees in the vicinity when the incident occurred, and their actions in response to the incident; recommendations of police advisors, employees or consultants; and actions taken by the facility in response to the incident. Violent event data will be requested for the three years preceding enactment of the legislation (2009-2011) and three years' post enactment (2012-2014). In keeping with the regulation's definition of a violent event and to standardize data collection across facilities, we will request incident reports that document physical assaults only. Based on our preliminary research in hospitals, workers are more inclined to report physical violence than verbal threats of violence, which gives us a level of confidence that underreporting will be minimal.

The purpose of the *self-administered survey* is to document the type and frequency of workplace violence prevention training nurses and home healthcare aides receive. The survey will include questions about nurses' knowledge and home healthcare aides' knowledge of the NJ regulations, whether they receive the training components mandated in the regulations and their experience with verbal and physical assaults in the previous year. The nurse survey was pilot-tested in Summer 2011 prior to full-scale administration. The home healthcare aide survey will be pilot-tested in the Fall 2012 prior to full-scale administration. A letter of introduction with information on consent will be included with the survey questionnaire. Names of nurses and home healthcare aides will not be recorded on the survey questionnaire and thus, their questionnaires will not be shared with their employers. The survey poses minimal risk to nurses and to home healthcare aides and human subjects review approval is not a problem.

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

The information collection does not involve web-based data collection for the nurse survey and home healthcare aide survey. There will be no content directed at children 13 years of age or younger.

A.2 Purpose and Use of Information Collection

The purpose of the interviews with the chairs of the Violence Prevention Committees is to measure compliance to the state regulations (violence prevention policies, reporting systems for violent events, violence prevention committee, written violence prevention plan, violence risk assessments, post incident response and violence prevention training). The purpose of collecting assault injury data from facility violent event reports 3 years pre-regulation (2009-2011) and 3 years post-regulation (2012-2014) is to evaluate changes in assault injury rates before and after enactment of the regulations. The nurse survey will describe the workplace violence prevention training nurses receive following enactment of the New Jersey regulations. The home healthcare aide survey will describe the workplace violence prevention training home healthcare aides receive following enactment of the New Jersey regulations.

The purpose of the information collected is to 1) compare the comprehensiveness of healthcare facility (hospital and nursing home) workplace violence prevention programs before and after enactment of the New Jersey regulations; 2) describe the workplace violence prevention training nurses and home healthcare aides receive following enactment of the New Jersey regulations; and 3) examine patterns of assault injuries to workers before and after enactment of the regulations.

The information will be collected only once. The data will be used to determine the impact of the New Jersey Violence Prevention in Health Care Facilities Act to reduce violence against healthcare workers. The data will be used by NIOSH researchers and collaborators only. Specifically, the data will be used for 1) preparation of papers for publication and reports to document the impact of the New Jersey Violence Prevention in Health Care Facilities Act, 2) dissemination of reports and recommendations to states considering introducing or amending similar workplace violence prevention legislation, to federal government agencies and to international healthcare systems, and 3) dissemination of research results to the public health community conducting workplace violence prevention research.

The *positive* need for this information is to document legislative best practice approaches that successfully reduce violence-related injuries to healthcare workers. Baseline data from the previous California/New Jersey National Institute of Occupational Safety & Health-funded study provides us a distinctive opportunity to measure compliance to the New Jersey regulations. Compliance with legislation can be difficult to measure due to the timing of enactment and implementation. Currently, the regulations to implement the Act have been developed by the New Jersey Department of Health and Senior Services and after an initial review and comment through the Health Care Administration Review Board, the regulations went to the New Jersey State Register on January 3, 2011. The public comment period ended on March 4th, 2011 at which time the New Jersey Department of Health and Senior Services will have to respond to all comments received. The regulations to implement the Act were issued on September 6, 2011 and apply to general acute care facilities, psychiatric hospitals and nursing homes. The regulations became effective in the Spring of 2012. Healthcare facilities will then have 3-6 months to comply with the state mandate. We are perfectly positioned to gather compliance information after the regulations have been implemented by the covered healthcare facilities. Also, the previous National Institute of Occupational Safety & Health-funded study was unable to measure the *change* brought about by the legislation, either in the components of workplace violence programs or in employee assault rates which the proposed study will be able to address. The proposed project will also include an evaluation of compliance with the regulations over the entire hospital and not just focus on the emergency room and behavioral health units. The California study focused on these units, but anecdotes suggested that substance abuse/detox and some medical/surgical units also had significant problems with violent incidents. In addition, we will also be surveying nurses independently which will allow for a more accurate representation of the population of nurses in these healthcare facilities. In the California study, workers were interviewed while at work and were most often selected for interview by the manager in charge or the hospital administration. In some instances, this resulted in a biased worker interview sample.

The *negative* consequences of not having the compliance information is that a high number of injuries will continue to occur to healthcare workers because NIOSH in accordance with its mandate did not move to disseminate successful legislation results to communities, to health departments, and to legislative bodies.

Privacy Impact Assessment Information

The information is being collected to examine healthcare facility (hospital and nursing home) compliance with the New Jersey Violence Prevention in Health Care Facilities Act, and to evaluate the effectiveness of the regulations in this Act in reducing assault injuries to workers (nursing staff and home healthcare aides). Results from the proposed project will contribute to the development and dissemination of a NIOSH numbered document, a r2p output, that outlines the benefits of comprehensive healthcare workplace violence prevention plans, including organizational- and worker-level barriers and facilitators to implementation. Currently, six states have legislation in place to reduce violence to healthcare workers, and many others have considered implementing laws. Findings from the proposed project can ultimately be valuable to states considering introducing or amending similar workplace violence prevention legislation, to federal government agencies, and to international healthcare systems.

The intended use of the information is for research purposes to 1) publish the findings in a peer-reviewed scientific journal, 2) publish the information in industry and healthcare association journals, 3) disseminate the information to health departments, and 4) to disseminate the information to the public health and criminology scientific community currently active in research to reduce workplace violence in the healthcare industry.

The facility name and address will never be documented on the data collection forms. Physical injuries will be collected from the hospital and nursing home incident reports. Violent event data abstraction will contain no personal identifying information on the victims, perpetrators or witnesses of the events. For the nurse survey, personal identifiable information on nurses will not be collected. For the home healthcare aide survey, personal identifiable information on home healthcare aides will not be collected.

No Information in Identifiable Form (IIF) will be collected. The impact of the proposed information collection on the privacy of individuals is minimal because there is no IIF data or sensitive data being collected on the individual.

A.3 Use of Improved Information Technology and Burden Reduction

In our pilot with 8 hospital facilities in the Fall 2010, violent event data were available electronically for all sites. For data available electronically, we will request a personal de-identified dataset that contains the variables required in the NJ regulations. For facilities where data are not available electronically, we will abstract on-site from hard-copy incident reports. Upon request from a facility, we will develop a standardized data use agreement to access violent event data. Dr. Blando will take primary responsibility for the abstraction from both on-site and electronic files. Ms. Emily O'Hagan R.N. (retired NJ Department of Health and Senior Services), who will work as a consultant on the proposed project, will assist Dr. Blando with data abstraction. Ms. O'Hagan was a key field staff member in the previous NIOSH-funded California legislation study. In addition, her experience in both clinical care and public health will have significant utility in this phase of the project. A reliability check of abstracted violent event data will be performed with an additional member of the research team.

The study team had abstracted employee hours data for emergency departments and behavioral health units in the previous study for the years 1992 - 2001, at which time the data were maintained via hard copy. However, since 2001 the NJDHSS has maintained the data in electronic formats. These electronic databases are considered public information and can be obtained via Open Public Records Act (OPRA) requests. The study team has already obtained the Form C data for all hospitals in NJ for the years 2005 - 2009 through a previous OPRA request. Data becomes available approximately one year after the data submission. Therefore, 2010 data will become available in June 2011.

The survey will include questions about nurses' knowledge and home healthcare aides' knowledge of the NJ regulations, whether they receive the training components mandated in the regulations and their experience with verbal and physical assaults in the previous year. We estimate the survey to take no more than 20 minutes to complete. The nurse survey was pilot-tested in Summer 2011 prior to full-scale administration. The home healthcare aide survey will be pilot-tested in the Fall 2012 prior to full-scale administration. A letter of introduction with

information on consent will be included with the survey questionnaire. Names of nurses and home healthcare aides will not be recorded on the survey questionnaire and thus, their questionnaires will not be shared with their employers. The survey poses minimal risk to nurses and home healthcare aides.

Electronic collection technique will be used for injury data collection, for the nurse survey and home healthcare aide survey. Hospitals will be visited by Dr. Blando and personal interviews of the Chair of Workplace Violence Prevention committee will be conducted. Nursing homes will be visited by Dr. Blando and personal interviews of the Chair of Workplace Violence Prevention committee will be conducted. Attempts were made to ensure the burden was as low as possible by collecting the hospital's policies and procedures before the interview. Attempts were made to ensure the burden was as low as possible by collecting the nursing home's policies and procedures before the interview. Letter of support have been obtained from the Health Professionals and Allied Employees (HPAE) union. The personal interview methodology was employed because this worked in the previous NIOSH study. The questionnaire and methodology were pilot tested in 8 healthcare facilities to ensure that the survey methodology was feasible, the questionnaire questions were not sensitive and could be answered by the hospital administrator, and that the length of the questionnaire was acceptable to the hospital administrator.

A.4 Efforts to Identify Duplication and Use of Similar Information

In preparation for the proposed project, we pilot-tested the data collection instrument to be used to interview administrators about the elements of their facility's workplace violence prevention programs. The pilot test was instrumental in improving the interview process and provided assurance that an interview will be an effective way of obtaining detailed information from administrators. The pilot test involved administration of the survey in a direct face-to-face interview at hospitals in an identical manner proposed for this project. The pilot was conducted with eight NJ healthcare facilities in October and November 2010. Facilities were selected to represent various hospital types, specifically acute care (general) and psychiatric hospitals, and sizes. Based on the pilot, we developed two data collection instruments, one as the interview form and the other to abstract data from the facility's written programs. To keep the interview to 45-60 minutes, the abstraction form was developed to obtain information on the facilities workplace violence prevention program, leaving the interview to provide more qualitative input into the barriers and facilitators to interpreting and implementing the NJ regulations.

Only one study (that of Drs. Peek-Asa and Casteel) has examined compliance to legislation mandating implementation of comprehensive workplace violence prevention programs in healthcare facilities for reducing violence to workers. The findings from our study will have useful policy implications for New Jersey and for other states looking to enact workplace prevention laws.

A.5 Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection.

A.6 Consequences of Collecting the Information Less Frequently

The information request is for a one-time collection only. There are no technical or legal obstacles to reduce the burden.

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

There are no special circumstances connected with the information collection.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency (101-442)

- A. A 60-day Federal Register Notice was published in the *Federal Register* on August 1, 2012, vol. 77, No. 148, pp. 45617-45618 (see Appendix B). We received one non-substantial comment (Appendix I).
- B. We consulted outside the agency with the University of Iowa, the University of North Carolina, and Old Dominion University.

A.9 Explanation of Any Payment or Gift to Respondents

The information collection does not propose to provide a payment or gift to the respondents.

A.10 Assurance of Confidentiality Provided to Respondents

Privacy Impact Assessment Information

A. This submission has been reviewed by CDC's Information Collection Review Office (ICRO), who determined that the Privacy Act does not apply.

B. Data collection in Phase I will include abstraction by the contractor from the facility's (hospital and nursing home) workplace violence prevention policies and procedures and interviews with the facility's violence prevention committee chair (who is the individual responsible for oversight of the program) and abstraction from the facility's violent event incident reports and administrative records. Data collection in Phase II will include self-administered survey of nurses and home healthcare aides.

Phase I: Facility (hospital and nursing home) survey

Abstraction from Workplace Violence Prevention Policies and Procedures: These data will be used to measure the compliance of the facility's workplace violence prevention program. At the time of recruitment, Dr. Blando will request a copy of the facility's workplace violence prevention policies, procedures and training materials. Receipt of these documents will be requested via email attachment. If not possible by email, we will provide a pre-paid, pre-addressed mailer to the facility for mailing the documents. Dr. Blando will abstract the information prior to the interviews with the violence prevention committee chair.

Interviews with Violence Prevention Committee Chairs: The purpose of these interviews is to supplement (and clarify, if needed) data abstracted from the policies, procedures and training

materials, as well as to obtain qualitative information about the chair's knowledge and attitudes about the NJ regulations. The interviews will utilize a standardized questionnaire designed for administration to the Chair of the Workplace Violence Prevention Committee. At the time of recruitment, Dr. Blando will schedule an interview to be conducted at the facility with the committee chair.

Violent Event Incident Reports and Administrative Records: These data will be used to measure changes in the incidence rate of employee violence before and after enactment and phased implementation of the NJ regulations. The violent event data will also be used to describe the circumstances surrounding the events. According to the regulations, facilities are required to gather the following information after a violent incident: date, time and location of the incident; identity, job title and job task of the victim; identity of the perpetrator; description of the violent act, including whether a weapon was used; description of physical injuries; number of employees in the vicinity when the incident occurred, and their actions in response to the incident; recommendations of police advisors, employees or consultants; and actions taken by the facility in response to the incident. In our pilot with 8 facilities in the Fall 2010, violent event data were available electronically for all sites. For data available electronically, we will request a personal de-identified dataset that contains the variables required in the NJ regulations. For facilities where data are not available electronically, we will abstract on-site from hard-copy incident reports. Upon request from a facility, we will develop a standardized data use agreement to access violent event data. Dr. Blando will take primary responsibility for the abstraction from both on-site and electronic files. Ms. Emily O'Hagan R.N. (retired NJ Department of Health and Senior Services), who will work as a consultant on the proposed project, will assist Dr. Blando with data abstraction. Ms. O'Hagan was a key field staff member in the previous NIOSH-funded California legislation study. Violent event data will be requested for the three years preceding enactment of the legislation (2009-2011) and three years' post enactment (2012-2014). In keeping with the regulation's definition of a violent event and to standardize data collection across facilities, we will request incident reports that document physical assaults only. Based on our preliminary research in hospitals, workers are more inclined to report physical violence than verbal threats of violence, which gives us a level of confidence that underreporting will be minimal.

Phase II: Nurse survey and Home Healthcare Aide Survey

Self-Administered Survey: The purpose of this survey is to document the type and frequency of workplace violence prevention training nurses and home healthcare aides receive. The survey will be mailed with a self-addressed, stamped envelope for return to the third-party contractor. The contractor will track and manage the mailing and response. The contractor will also enter the survey data and send the completed de-identified tracking and survey databases to NIOSH. The survey will include questions about nurses' knowledge and home healthcare aides' knowledge of the NJ regulations, whether they receive the training components mandated in the regulations and their experience with verbal and physical assaults in the previous year. We estimate the survey to take no more than 20 minutes to complete. A letter of introduction with information on consent will be included with the survey questionnaire. Names of nurses and home healthcare aides will not be recorded on the survey questionnaire and thus, their questionnaires will not be shared with their employers.

Data will be stored in a secure manner and will not be disclosed unless otherwise compelled by law. All forms will be kept in locked cabinets. All electronic files will be kept in secure,

password protected folders. Only approved project connected personnel will have access to the hardcopy and electronic records. Since no personal identifiers will be collected, contract interviewers will not be subject to a nondisclosure agreement.

C. Facility (Hospital and Nursing Home) Survey: The letter of introduction and fact sheet will be sent to the Chair of the Violence Prevention committee introducing the study and the benefits of participation by Dr. Blando. Verbal consent from the Chair of the Violence Prevention committee to participate will be obtained by Dr. Blando. The information to be collected, the intended uses of the data, the minimal risk connected with their participation, and who to contact in the event of liability will be explained to them by Dr. Blando.

Nurse Survey and Home Healthcare Aide Survey: The survey will be mailed with an introduction letter explaining the purpose of the survey, consent process and instructions for completing and mailing it back. For nurses and home healthcare aides who choose not to complete the survey, we will ask that they return it blank with an indicator at the top that they are opting out.

D. Respondents will be informed that their participation in providing information is voluntary. The Privacy Act does not apply, however intended use of the data and the minimal risk in participation will be explained to them. There will be no effect on the Chairs of the Violence Prevention committee or nurses or home healthcare aides who refuse to participate and do not reply to the information request.

A.11 Justification for Sensitive Questions

There are questions on the survey instrument which could be considered sensitive by some responders such as age, sex, and length of employment. These questions are necessary so that we can compare workplace violence injury rates between nurses before and after the ordinance while controlling for the socio-demographic categories which may increase the risk of injuries. Asking participants to recall instances of workplace violence may also be sensitive, depending on the circumstance of the incident. As the survey is voluntary, respondents may refuse to answer any questions. Respondents are informed of their right to refuse participation and their right to refuse to answer individual questions in the introductory letter. Additionally, respondents will be informed that their personal identifiers will not be recorded and their information provided will not be linked to them. While these questions may be difficult to answer for some respondents, these answers are needed to allow us to measure and control for important risk factors for workplace violence which may modify the effect of the ordinance.

Appendix E contains the current HSRB approval letter.

A.12 Estimates of Annualized Burden Hours and Costs

- A. Hospital:** The interview with the Chair of the Workplace Violence Prevention Chair of 50 hospital healthcare facilities will take approximately 60 minutes, resulting in an annualized burden estimate of 17 hours. Conducting the interview by the contractor with the Chair of the Workplace Violence Prevention Chair of 50 hospital healthcare facilities

will take approximately 60 minutes and collecting the injury data will take approximately 60 minutes (contractor 2 hours per hospital), resulting in an annualized burden estimate of 33 hours.

Nursing Home: The interview with the Chair of the Workplace Violence Prevention Chair of 20 nursing home facilities will take approximately 60 minutes, resulting in an annualized burden estimate of 7 hours. Conducting the interview by the contractor with the Chair of the Workplace Violence Prevention Chair of 20 nursing home facilities will take approximately 60 minutes and collecting the injury data will take approximately 60 minutes (contractor 2 hours per nursing home), resulting in an annualized burden estimate of 13 hours.

Nurse Survey: The survey of nurses may be completed within 6 months. The sample size for the survey is designed to include 4000 nurses. The questionnaire is a one-time survey which takes approximately 20 minutes to complete, resulting in an annualized burden estimate of 444 hours.

Home Healthcare Aide Survey: The survey of home healthcare aides may be completed within 6 months. The sample size for the survey is designed to include 4000 home healthcare aides. The questionnaire is a one-time survey which takes approximately 20 minutes to complete, resulting in an annualized burden estimate of 444 hours.

The total annualized burden estimate is 960 hours.

Estimated annualized Burden Hours

Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hrs)	Total Burden (in hrs)
Hospital Administrators	Evaluation of Hospital Workplace Violence Prevention Program (C1)	17	1	1	17
Hospital Administrators	Committee Chair Interview (C2)	17	1	1	17
Hospital Administrators	Employee Incident Information (C3)	17	1	1	17
Nursing Home Administrators	Evaluation of Nursing Home Workplace Violence	7	1	1	7

	Prevention Program (C1)				
Nursing Home Administrators	Committee Chair Interview (C2)	7	1	1	7
Nursing Home Administrators	Employee Incident Information (C3)	7	1	1	7
Nurses (RN and LPN)	Healthcare Facility Workplace Violence Prevention Programs Nurse Survey (C4)	1333	1	20/60	444
Home Healthcare Aides	Healthcare Facility Workplace Violence Prevention Programs Home Healthcare Aide Survey (C5)	1333	1	20/60	444
Total					960

B. An estimate of the annualized burden costs is provided below using Bureau of Labor Statistics (BLS) estimate wages by occupation.

Estimates of Annualized Burden Costs

Type of Respondent*	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Hospital Administrators	17	\$50.69	\$862
Nursing Home Administrators	7	\$50.69	\$355
Nurses (RN and LPN)	444	\$26.22	\$11,642
Home Healthcare Aides	444	\$10.49	\$4,658

Total			\$17,517
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* These estimates are calculated using the U.S. Department of Labor's National Occupational Employment and Wage Estimates for the United States. May, 2009. (http://www.bls.gov/oes/current/oes_nat.htm#11-0000). Salaries for hospital administrators were estimated to be that of the BLS category of management occupations. Salaries for nurses (RN and LPN) were taken to be the BLS category of that of Registered Nurses (\$32.56) and Licenses Practical Nurses (\$19.88)[average=32.56+19.88/2=26.22]. The total annualized burden costs are \$17553.

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

There are no additional cost burdens for respondents.

A.14 Annualized Cost to the Government

The annualized cost to the government for this project is estimated to be \$964,367. The table below summarizes a breakdown of the estimated costs.

Item	FY 2011	FY 2012	FY2013	Total
<u>Discretionary costs:</u>				
Equipment and supplies ¹	\$500	\$500	\$500	\$1500
Contractual	\$336192	\$154725*	\$74798~	\$565715
Travel	\$5000	\$5000	\$8000^	\$18000
Total Discretionary	\$341692	\$160225	\$83298	\$585215
Total Personnel and benefits	\$120270	\$126284	\$132598	\$379152
Total cost to Federal Government	\$461962	\$286509	\$215896	\$964367

*\$68446 (original) + \$86279 (Home Healthcare Aide Survey)

~\$30798 (original) + \$44000 (Nursing Home Study)

^\$5000 (original) + \$3000 (Nursing Home Study)

FY12 Additional \$86279

FY13 Additional \$47000

A.15 Explanation for Program Changes or Adjustments

The burden hours currently approved for nurses and hospital administrators were not annualized in the initial submission. This has been corrected, and results in a decrease from the previously approved numbers.

This revised data collection adds two new respondent groups (Nursing Home Administrators and Home Healthcare Aides). This addition results in an increase in the number of responses and burden hours.

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

Clearance is being requested for 36 months, starting in January, 2013 and continuing through January, 2016. OMB approval is anticipated by December, 2012 which will afford time to

complete the nursing home sample selection, send out notification letters, and kick-off the survey of nursing homes by June, 2012. A critical date to begin data collection is January 2013 which will allow NIOSH to collect data 1.5 year after the regulations are effective.

We plan to publish project results in peer reviewed scientific journals with a high impact number. Additionally, results will be presented at national, scientific conferences with high public visibility to research audiences, and at trade associations such as the Hospital Associations in order to reach both industry and community leaders that are empowered to promulgate legislative ordinances for healthcare worker safety. Results will also be disseminated to stakeholder groups via presentation and written reports. Stakeholder groups include the NJ Health Department, NJ legislative entity, HPAE and the NJ Hospital Association.

Activity	Time Schedule
Obtain sampling frame for hospitals, nursing homes, nurses and home healthcare aides	9 months prior to and 1 month after OMB approval
Draw sample from sampling frame 9 month prior to OMB approval	9 month prior to OMB approval
Award survey support contract	3 months prior to OMB approval
Draw final sample from sampling frame 1 month after OMB approval	1 month after OMB approval
Begin interviews with Chair of Workplace Violence Prevention committee	2 months after OMB approval
Complete interviews	12 months after OMB approval
Complete cleaning of data and database development	12-15 months after OMB approval
Complete statistical analysis	15-24 months after OMB approval
Complete papers and reports for publication in peer-review journals & trade association journals & publications.	24-36 months after OMB approval
Complete presentations to research audiences and stakeholders	24-36 months after OMB approval

The analysis plan is described as follows:

Specific Aim 1: *Compare the comprehensiveness of healthcare facility workplace violence prevention programs before and after enactment of the NJ regulations*

Working Hypothesis: Enactment of the NJ regulations will improve the comprehensiveness of hospital and nursing home workplace violence prevention program policies, procedures and training.

Statistical Power Calculation for Hospitals: Fifty hospitals will be sampled to address this aim. Using 50 hospitals as the target enrollment, statistical power to detect a significant increase in the comprehensiveness of hospital workplace violence prevention programs following enactment of the regulations is provided in Table 1. Final compliance rates ranging from 80% to 95% were selected based on suggested rates found in California hospitals from the previous NIOSH-funded study after enactment of similar legislation. This increase is based on an average baseline comprehensiveness rate of approximately 70% from the California study. Based on the findings from Table 1, we will have sufficient power to detect a meaningful increase in the

comprehensiveness of hospital workplace violence prevention programs by enrolling 50 hospitals.

Table 1: Statistical power for varying levels of compliance after enactment.

<u>Final Compliance Rate</u>	<u>Power</u>
95%	100.0%
90%	99.9%
85%	98.3%
80%	79.1%

Statistical Analysis for Hospitals: Two measures of comprehensiveness will be created: (1) baseline measure to represent the degree to which hospitals already have the components of the NJ regulations in place prior to enactment, and (2) compliance measure to represent the degree to which hospitals have the components of the NJ regulations in place following enactment. Both baseline and compliance measures will be scored by category of the regulation. These categories include violence prevention policies, reporting systems for violent events, violence prevention committee, violence risk assessments, post incident response, and violence prevention training. Within each category, hospitals are required to implement specific components. Therefore, baseline comprehensiveness and compliance will be measured using a score for each category. The score will be calculated as the proportion of the total number of regulation components each hospital has in place, where each hospital will be given one point per component. We will not assign weights to the components because there is no precedent for assuming the presence of one component is more important than the presence of another. Baseline component scores, by category of the regulations, are available from the previous NIOSH-funded study for New Jersey hospitals. Compliance component scores will be calculated using data collected in the proposed project.

Baseline comprehensiveness and compliance scores will be compared using paired t-tests. Comparisons by hospital type, as well as categories of operations data (e.g., number of hospital beds, number of patients per year, amount of charity care rendered, and hospital control) will also be examined. Amount of charity care rendered is defined as care given to persons with modest resources without standard compensation for that care. Hospital control will be defined into categories of for-profit and non-profit.

Statistical Power Calculation and Statistical Analysis Plan for Nursing Homes: Assess the increase in compliance in NJ nursing homes by comparing the change in compliance pre-regulation versus post-regulation for NJ nursing homes compared to the same change in compliance in VA nursing homes. This will be analyzed by calculating the proportion of nursing homes which went from non-compliant in the pre-regulation time to compliant in the post-regulation time for each state, and then comparing the proportions for each state by employing 95% confidence intervals based on the binomial distribution. Assuming that both states have pre-regulation compliance rates of 10%, NJ nursing homes increase to 50% and VA nursing homes remain at 10% post-regulation, a simulation study based on 10,000 simulations determined that we will have 87% power based on sampling 20 nursing homes in each state. Two measures of comprehensiveness will be created: (1) baseline measure to represent the degree to which nursing homes already have all of the components of the NJ regulations in place prior to enactment, and (2) compliance measure to represent the degree to which nursing homes have all of the components of the NJ regulations in place following enactment. Both baseline and compliance measures will be scored either as having all components of the regulation or not

having all components. These components include violence prevention policies, reporting systems for violent events, violence prevention committee, violence risk assessments, post incident response, and violence prevention training. Within each component, nursing homes are required to implement specific elements. Baseline and compliance measures will be collected during the interviews. We will also look at degrees of compliance with the different pieces of the legislative requirements.

Specific Aim 2: Describe the workplace violence prevention training nurses and home healthcare aides receive following enactment of the NJ regulations

Working Hypothesis: Nurses and home healthcare aides receive at least 80% of the workplace violence prevention training components mandated in the NJ regulations.

Statistical Power Calculation for Nurse Survey: A total of 4000 nurses will be surveyed using a stratified random sampling design. Nurses will be stratified by licensed practical nurses (LPNs) and registered nurses (RNs). Home healthcare aides will not be stratified. The power calculation for this aim is based on an aggregate measure of worker knowledge of the facility’s workplace violence prevention training program. The sampling errors for estimated proportions of knowledge based on the nurse’s responses are presented in Table 2.

Table 2. Sampling errors for estimated proportion of nurses and of home healthcare aides who received 80% of training components based on a sample of 2000 (50% response rate) and on a sample of 3000 (75% response rate).

Sample Size of 2000		Sample Size of 3000	
<u>Estimated Proportion</u>	<u>Sampling Error</u>	<u>Estimated Proportion</u>	<u>Sampling Error</u>
10%	±1%	10%	±1%
25%	±2%	25%	±2%
50%	±2%	50%	±2%
75%	±2%	75%	±2%
90%	±1%	90%	±1%

Statistical Analysis for Nurse Survey: A comprehensiveness score for nurse and for home healthcare aide training in workplace violence prevention will be calculated as the proportion of training components nurses identify as having received by their hospitals, where the denominator is the total number of components mandated in the NJ regulations. This comprehensiveness measure will be calculated post-enactment of the NJ legislation. Weights will not be assigned to the components of the regulations because there is no precedent for assuming one component is more important than another.

Post-enactment comprehensiveness scores will be compared across hospital type and worker characteristic categories (i.e., job title, hospital department, shift) using t-tests and ANOVA. Nonparametric options will be considered if distributions vary from normality. Since there are 50,050 RNs and 1,600 LPNs working in hospitals in NJ, there will be a need to over-sample LPNs so that we can do a comparison between RNs and LPNs. Therefore, a sampling weight for each nurse will also be incorporated into this analysis. Finite corrections to the variance of the estimates will also be calculated in this analysis based on the population totals in the data frame.

Specific Aim 3: Examine patterns of assault injuries to workers (hospital and nursing home) before and after enactment of the regulations

Hypothesis: The rates of assault injuries to workers (hospital and nursing home) will decrease following enactment of the regulations.

Statistical Power Calculation for Hospital Workers: A stratified random sample will be selected based on the provided sampling frame of hospitals (see Section C.4.II). Five strata will be created based on the five facility types: Trauma I, Trauma II, GAC < 300 beds, GAC >= 300 beds, Psychiatric. A sample of 10 hospitals will be selected in each of the five strata so that a total of 50 hospitals will be selected. Weights will be calculated for each hospital within a specific stratum by dividing the total number of hospitals in that stratum by the number of hospitals randomly selected within that stratum. Based on assault injury rates (48% decrease in emergency departments and 37% decrease in psychiatric units) from Casteel et al³, we anticipate having 87% power to detect a 40% decrease in assault injury rates following enactment of the regulations.

Statistical Analysis for Hospital Workers: A Poisson regression model will be selected to assess the effectiveness of the regulations in reducing rates of physical assault injury before the regulations were enacted (2008-2011) compared to after the regulations were enacted (2012-2014). The number of physical assault injuries for each hospital will be modeled to identify potential statistical confounders both before and after the regulations by year. The logarithm of employee hours per year at each hospital will be used as an offset variable so that rates are modeled. The weight associated with each hospital will be incorporated in this analysis. Generalized Estimating Equations will be used for the Poisson regression assuming each separate hospital as a cluster.

We will examine patterns of physical assault injury before and after enactment of the regulations by hospital type, hospital control and rates of community crime surrounding the hospital. These variables will be measured as effect-measure modifiers based on findings from the previous NIOSH-funded study^{3,6}. Hospital type and hospital control are defined in previous sections. Community crime will be defined as town-level index and violent crime obtained through Uniform Crime Reports. Community crime rates will be calculated as the number of index and violent crimes per 100,000 town population per year, where population size will be obtained through the U.S. Census Bureau.

The components of a hospital's workplace violence prevention program will also be examined as a potential effect-measure modifier. The total components will be defined as the average score across each regulation category (see Specific Aim 1 for definitions). This average score will be categorized into tertiles of high, medium and low for analysis. Depending on the distribution, we may also categorize program components based on the percentage of components in place (e.g., hospital has at least 50% of the components in place, where the reference category is having less than 50% of the components in place).

Statistical Power Calculation and Statistical Analysis Plan for Nursing Home Workers: Generalized estimating equations with a Poisson model will be employed for an event-level analysis to examine rates of assault injury pre- and post- enactment of the regulations. The numerator for the rates will be the number of assaults abstracted from nursing home violent event reporting systems and the denominator will be the number of employees per nursing home abstracted from financial data available through the New Jersey Department of Health and

Senior Services. Assuming that the rate of violent incidents pre-regulation is 0.8 incidents per nurse per year, and there are approximately 72 nurses exposed in each nursing home, we will have nearly 100% power to detect a 20% decrease in incidents post-regulation in a 20 nursing home in each state study.

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

The OMB expiration date will be displayed on all Questionnaires (Interview form, Hospital and Nursing Home Abstraction form, Violent Event Injury form, Nurse Survey and Home Healthcare Aide Survey).

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.