

## Opioid Overdose Prevention Programs

Effective date: 7/30/14

Pursuant to the authority vested in the Commissioner by Public Health Law Section 3309(1), section 80.138 of Part 80 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, is amended to read as follows, effective upon publication of a Notice of Adoption in the New York State Register:

### **PART 80**

#### **RULES AND REGULATIONS ON CONTROLLED SUBSTANCES**

(Statutory authority: Public Health Law, Sections 3308 and 3309(1))

Sec.

#### **GENERAL PROVISIONS**

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Section 80.138. Opioid Overdose Prevention Programs.

(a) Definitions.

(1) [Clinical director means a physician, physician assistant or nurse practitioner who provides oversight of the clinical aspects of the Opioid Overdose Prevention Program. This oversight includes serving as a clinical advisor and liaison concerning medical issues related to the Opioid Overdose Prevention Program, providing consultation on training and reviewing reports of all administrations of an opioid antagonist.

(2)] Opioid means an opiate as defined in section 3302 of the Public Health Law.

[(3)] (2) Opioid antagonist means an FDA-approved drug that, when administered, negates or neutralizes in whole or in part the pharmacological effects of an opioid in the body. The opioid antagonist is limited to naloxone or other medications approved by the department for this purpose.

[(4)] (3) Opioid [O]overdose [P]prevention [P]program means a program the purpose of which is to train individuals to prevent a fatal opioid overdose in accordance with these regulations.

[(5)] (4) Opioid [Overdose Prevention Training Program] overdose prevention training curriculum [means a training program offered by an authorized Opioid Overdose Prevention Program which instructs a person to prevent opioid overdoses,] refers to any set of instructions, consistent with guidance from the department, which provides a person encountering a suspected opioid overdose with the steps to take for preventing a fatality, including by providing resuscitation, contacting emergency medical services and administering an opioid antagonist.

(6) Person means an individual other than a licensed health care professional, law enforcement personnel, and first responders otherwise permitted by law to administer an opioid antagonist.

(7) Program director means an individual who is identified to manage and have overall responsibility for the Opioid Overdose Prevention Program.

(8)] (5) Registered provider for the purposes of this section shall mean any of the following that have the services of both a program director and a clinical director and that have registered with the department pursuant to subdivision (b) of this section:

- (i) a health care facility licensed under the Public Health Law;
- (ii) a physician, physician assistant, or nurse practitioner who is authorized to prescribe the use of an opioid antagonist;
- (iii) a drug treatment program licensed under the Mental Hygiene Law;
- (iv) a not-for-profit community-based organization incorporated under the Not-for-profit Corporation Law [and having the services of a clinical director];
- (v) a local health department or other local government agency;
- (vi) an institution of higher education, recognized and approved by the regents of the university of the state of New York, which provides a course of study leading to the granting of a post-secondary degree or diploma; and
- (vii) a business, trade, technical or other occupational school approved as such by the regents of the university of the state of New York or accredited by a nationally recognized accrediting agency or association accepted as such by the regents of the state of New York.

(6) Program director means an individual who is identified to manage and have overall responsibility for the opioid overdose prevention program.

(7) Clinical director means a physician, physician assistant or nurse practitioner who is designated in an opioid overdose prevention program's registration for prescribing

an opioid antagonist to trained overdose responders and who provides oversight of the clinical aspects of the opioid overdose prevention program. This oversight includes serving as a clinical advisor and liaison concerning medical issues related to the opioid overdose prevention program, providing consultation on training and reviewing reports of all administrations of an opioid antagonist.

(8) Affiliated prescriber means a physician, physician assistant or nurse practitioner, who, in addition to the clinical director, is designated in an opioid overdose prevention program's registration for prescribing an opioid antagonist to trained overdose responders.

(9) Trained overdose responder means [a person] any individual who has successfully completed an [authorized Opioid Overdose Prevention Training Program] opioid overdose prevention training curriculum offered by an authorized [O]opiod [O]overdose [P]prevention [P]program within the past two years and has been authorized by a registered provider to possess the opioid antagonist.

(b) Registration.

(1) Registered providers may operate an [O]opiod [O]overdose [P]prevention [P]program if they obtain a certificate of approval from the department authorizing them to operate an [O]opiod [O]overdose [P]prevention [P]program and otherwise comply with the provisions of this section.

(2) Providers eligible to register to operate an[d] [O]opiod [O]overdose [P]prevention [P]program that are in good standing may apply to the department to

operate an [O]opiod [O]overdose [P]prevention [P]program on forms prescribed by the department which must include, at a minimum, the following information:

(i) the provider name, address[,] and operating certificate or license number where appropriate[, telephone number, fax number, e-mail address, program director and clinical director];

(ii) the name, address, telephone number, fax number, e-mail address and signature of the program director;

(iii) the name, address, telephone number, fax number, e-mail address, license type, license number and signature of the clinical director,

[(ii)] (iv) the name, license type and license number of the affiliated [prescriber(s)] prescribers, if any;

[(iii)] (v) the name and [location] address of the [site(s)] sites at which the [O]opiod [O]overdose [P]prevention [P]program will be conducted; and  
[(iv)] (vi) a description of the targeted population to be served and recruitment strategies to be employed by the [O]opiod [O]overdose [P]prevention [P]program[; and].

[(v) the addresses, telephone numbers, fax numbers, e-mail addresses and signatures of the program director and clinical director.]

(c) Program operation.

(1) Each [O]opiod [O]overdose [P]prevention [P]program shall have a program director who is responsible for managing the [O]opiod [O]overdose [P]prevention [P]program and shall, either directly or through a designee, at a minimum:

- (i) identify a clinical director to oversee the clinical aspects of the [O]opioid  
[O]overdose [P]prevention [P]program;
- (ii) establish the content of [the training program,] the program's opioid overdose  
prevention training curriculum[, which meets the approval of the department];
- (iii) identify and train other program staff;
- (iv) select and identify persons as trained overdose responders;
- (v) issue certificates of completion to trained overdose responders who have  
successfully completed the [prescribed program] program's opioid overdose prevention  
training curriculum;
- (vi) establish and maintain the [O]opioid [O]overdose [P]prevention [P]program's  
mandated [records] recordkeeping system [including trained overdose responder training  
records, Opioid Overdose Prevention Program usage records and inventories of Opioid  
Overdose Prevention Program supplies and materials];
- (vii) ensure that all trained overdose responders successfully complete [all  
components of Opioid Overdose Prevention Training Program] the program's opioid  
overdose prevention training curriculum;
- (viii) provide liaison with local emergency medical services and emergency  
dispatch agencies, where appropriate;
- (ix) assist the clinical director with review of reports of all overdose responses,  
particularly those [including opioid antagonist administration] involving administration  
of an opioid antagonist; and

(x) report all administrations of an opioid antagonist on forms prescribed by the department.

(2) Each [O]opioid [O]overdose [P]prevention [P]program shall have a clinical director who is responsible for clinical oversight and liaison concerning medical issues related to the [O]opioid [O]overdose [P]prevention [P]program and, at a minimum, shall:

- (i) provide clinical consultation, expertise, and oversight;
- (ii) serve as a clinical advisor and liaison concerning medical issues related to the [O]opioid [O]overdose [P]prevention [P]program;
- (iii) provide consultation to ensure that all trained overdose responders are properly trained;
- (iv) adapt and approve [training program] opioid overdose prevention training curriculum content and protocols; and
- (v) review reports of all administrations of an opioid antagonist.

(3) The trained overdose responders shall:

- (i) complete an initial [Opioid Overdose Prevention Training Program] training consistent with the program's opioid overdose prevention training curriculum;
- (ii) complete a refresher [Opioid Overdose Prevention Training Program] training consistent with the opioid overdose prevention training curriculum at least every two years;

- (iii) contact [the] an emergency medical [system] service [during any response to] when encountering a victim of a suspected drug overdose and advise responding emergency medical services personnel if an opioid antagonist [is being] has been used;
- (iv) comply with protocols for response to victims of suspected drug overdose consistent with the program's opioid overdose prevention training curriculum; and
- (v) report all responses to victims of suspected drug overdose to the [O]opioid [O]overdose [P]prevention [P]program director or designated staff.

(4) The opioid antagonist shall be [dispensed] provided to the trained overdose responder in accordance with all applicable laws, rules and regulations.

(5) The [O]opioid [O]overdose [P]prevention [P]program will maintain and provide response supplies including: latex gloves, mask or other barrier for use during rescue breathing, and, in those programs which furnish an injectable formulation of naloxone, an agent to prepare skin before injection.

(6) The [O]opioid [O]overdose [P]prevention [Program will establish and maintain a] program's recordkeeping system [that will] must include, at a minimum, the following [information] elements:

- (i) [list] the names of trained overdose responders, [including dates of completion of training] the dates they were trained, and the dates they were furnished naloxone;
- (ii) a log of opioid overdose prevention trainings which have been conducted;]
- [(iii)] (ii) [copies of] program policies and procedures;
- [(iv)] (iii) copy of the contract/agreement with the clinical director, if appropriate;

[(v)] (iv) opioid antagonist administration usage reports and forms; [and]  
[(vi)] (v) documentation of review of administration of an opioid antagonist[.];  
and

(vi) an inventory of overdose response supplies.

(7) The [O]opiod [O]overdose [P]prevention [P]program will establish a procedure by which any administration of opioid antagonist to another individual by a trained overdose responder affiliated with an [O]opiod [O]overdose [P]prevention [P]program, shall be reported on forms prescribed by the department.

(8) Approval obtained pursuant to this section shall consist of a certificate of approval provided by the department that shall remain in effect for two years or until receipt by the authorized provider of a written notice of termination of the program from the department, whichever shall first occur. The department may renew a certificate of approval for a subsequent two-year period if the registered provider is in good standing with all applicable State and Federal licensing agencies and such provider is found to have complied with the requirements of this section [and has submitted a request for renewal].

(9) Pursuant to Public Health Law, section 3309(2) the purchase, acquisition, possession or use of an opioid antagonist by an [O]opiod [O]overdose [P]prevention [P]program or a trained overdose responder in accordance with this section and the training provided by an authorized [O]opiod [O]overdose [P]prevention [P]program

shall not constitute the unlawful practice of a profession[al] or other violation under title 8 of the Education Law or article 33 of the Public Health Law.

## **REGULATORY IMPACT STATEMENT**

### **Statutory Authority:**

Chapter 413 of the Laws of 2005, effective April 1, 2006, added Section 3309 of the Public Health Law to provide for opioid overdose prevention programs in New York State (NYS). Pursuant to PHL Section 3309(1), the Commissioner of Health is authorized to establish standards for approval of opioid overdose prevention programs.

### **Legislative Objectives:**

This legislation was enacted in order to reduce the incidence of fatal opioid overdoses by making possible the timely, appropriate and safe administration of life-saving medication on an emergency basis to individuals who experience accidental opioid drug overdoses. To further this objective, the regulations must support a broad range of qualified organizations in becoming registered opioid overdose prevention programs and do so in a way that is not needlessly burdensome or confusing. The revised regulations achieve this by expanding the eligible provider base to include local government agencies, other than local health departments which were already eligible; institutions of higher education recognized and approved by the Regents of the University of the State of New York which provide a course of study leading to the granting of a post-secondary degree or diploma; and business, trade, technical or other occupation schools approved as such by the regents of the university of the State of New York or accredited by a nationally recognized accrediting agency or association accepted as such by the regents of the State of New York.

The revised regulations also eliminate an unnecessary recordkeeping requirement and add clarity to entities considering registering as opioid overdose prevention programs by defining the role of affiliated prescribers and by eliminating potentially confusing language regarding the provision of overdose prevention training by the registered programs.

### **Needs and Benefits:**

Overdose is a preventable cause of death in the majority of cases involving opioids. Opioids include heroin as well as prescribed analgesics such as morphine, codeine, methadone, oxycodone (Oxycontin, Percodan, Percocet) and hydrocodone (Vicodin). In an opioid overdose, the user becomes sedated and gradually loses the urge to breathe, leading to death from respiratory depression. Naloxone is an opioid receptor antagonist that can be used to reverse an opioid overdose, generally within 1-2 minutes of administration. An untreated opioid overdose may result in death over the course of 1-3 hours. Approximately half of all injection drug users (IDUs) experience at least one nonfatal overdose during their lifetime.

According to the Centers for Disease Control and Prevention (CDC) drug overdose deaths are now the leading cause of accidental death in the United States for people aged 25-64. Of the 22,134 deaths relating to prescription drug overdose nationally in 2010, 16,651 (75%) involved opioid analgesics (also called opioid pain relievers or prescription painkillers). In 2011, drug misuse and abuse caused about 2.5 million emergency

department (ED) visits. Of these, more than 1.4 million ED visits were related to pharmaceuticals.

In New York State we are seeing substantial mortality associated with opioids. In 2012, there were 875 deaths where the toxicology reports indicated opioid analgesics. In addition, there were 478 overdose deaths that year associated with heroin and 150 deaths for which the toxicology report indicated an unspecified opioid.

The New York State Office of Alcoholism and Substance Abuse Services (OASAS) estimates that there are approximately 200,000 heroin users in New York State. In 2009, there were 14,010 admissions for primary diagnosis pertaining to a prescription opioid pain reliever and 27,496 for any diagnosis (primary, secondary or tertiary) pertaining to a prescription opioid pain reliever.

Most overdoses are not instantaneous and the majority of them are witnessed by others. Therefore, many overdose fatalities are preventable. Prevention measures include education on risk factors (such as polydrug use and recent abstinence), recognition of the overdose and an appropriate response. Response includes contacting emergency medical services (EMS) and providing resuscitation while awaiting the arrival of EMS. Resuscitation consists of rescue breathing, and, when available, administration of naloxone which immediately reverses the effects of heroin overdose. Naloxone is an opioid antagonist with no abuse potential and no effect on a recipient who has not taken opioids. Provision of naloxone has been suggested for many years and is being offered in

a variety of settings in jurisdictions outside of NYS. Complications of naloxone in the medical setting are rare.

Opioid overdose prevention programs, including those regulated by the current regulation, have proven effective in preventing unnecessary deaths. As of March 31 2014, over 130 programs have registered as Overdose Prevention Providers and over 60,000 naloxone kits have been distributed by NYSDOH. As of that same date, there were 850 reports of overdose reversals with the naloxone kits. Seventy-one percent of the people who received naloxone because of a drug overdose were between the ages of 18-45 and the vast majority had injected heroin and frequently opioids were used in combination with alcohol and other drugs. The largest number of reversals have been reported from New York (Manhattan) (203, 23.9%) and Erie (165, 19.422%) counties.

The proposed amendment to the rule achieves the following: 1) expanded provider eligibility so as to include institutions of higher education; business, trade, technical and occupational schools; and a wider range of local government agencies than was previously permitted; 2) elimination of an unnecessary recordkeeping requirement; 3) a clear definition of “affiliated prescribers”; and 4) an improved framing of training within the context of the regulated programs. The anticipated benefits under the proposed rule change are: reduced incidence of fatal opioid overdoses, increased contact of opioid users with medical personnel, greater awareness of risk factors for overdose, increased knowledge of safer injection practices and an increased number of persons trained in rescue breathing. The minor changes in opioid overdose prevention program

regulations—just like the initial implementation of the opioid overdose prevention program under the original regulations—will not lead to increased drug use. Naloxone is not addictive and does not cause a “high.” It has no potential for abuse or street value.

**Costs:**

There are no new mandates. This regulation continues to allow, not require, creation of opioid overdose prevention programs. Costs for the implementation of and continuing compliance to those parties that elect to establish such programs will continue to be minimal. As was past practice, no registration fee is being collected and the reporting requirements are minimal. A one-time, application process remains in effect in order for an opioid overdose prevention program to receive a certificate of approval. Existing staff can serve as the Program Director. Internal operational policies and procedures, as well as the training of staff, remain as requirements. Costs of necessary supplies and materials are minimal. Record keeping under the amended regulations has been simplified, and the reporting requirements are minimal and consistent with Public Health Law.

**Local Government Mandates:**

For purposes of implementing amendments to Article 3309 of the Public Health Law, local county health departments will continue to be made aware of the option to voluntarily offer opioid overdose prevention programs. Other local government agencies will also be informed of this option. Local EMS will continue to receive information concerning opioid overdose prevention.

**Paperwork:**

The NYSDOH anticipates a continued simple and streamlined process for eligible organizations to obtain a certificate of approval to establish an opioid overdose prevention program. The record keeping and reporting requirements imposed on the program are minimal, and some recordkeeping will actually be reduced under the amended regulation. Only those providers voluntarily participating will be required to provide information to the department.

**Duplication:**

The proposed amendments to the regulation do not duplicate any existing state or federal law or regulation regarding opioid overdose prevention.

**Alternatives:**

The proposed amendments to the regulation do not exceed the specific requirements of the legislation. Because offering an opioid overdose prevention program is voluntary, the regulation was designed to encourage eligible individuals and organizations to provide opioid overdose prevention services allowed under law and regulation. The approval process continues to be simple; and the reporting and financial impact of establishing a voluntary opioid overdose prevention program remains minimal. Any other alternatives would require a more complex and more costly approach for both the NYSDOH and volunteer operators of opioid overdose prevention programs.

**Federal Standards:**

The rule does not exceed any minimum standards of the federal government for the same or similar subject areas.

**Compliance Schedule:**

Each individual or organization that chooses to establish an opioid overdose prevention program must submit an initial application to the Department. Information on approved programs is then used to develop a listing of opioid overdose prevention programs, which is shared with the public. Applications for approval to establish opioid overdose prevention programs will continue to be accepted on an ongoing basis, with review and renewal happening at two-year intervals.

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## **REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS**

### **Effect of Rule:**

The proposed rule will have minimal impact on small businesses and local governments.

There are new potential opioid overdose prevention providers under the amended regulations: local government agencies, other than local health departments which were already eligible; institutions of higher education recognized and approved by the Regents of the University of the State of New York which provide a course of study leading to the granting of a post-secondary degree or diploma; and business, trade, technical or other occupation schools approved as such by the Regents of the University of the State of New York or accredited by a nationally recognized accrediting agency or association accepted as such by the regents of the State of New York. None of those entities would be required to maintain an overdose prevention program; rather they may voluntarily choose to have such program. The minimal impact on small businesses and local governments is underscored by the modest nature of opioid overdose prevention programs; no fee is required for approval, ongoing technical assistance is provided at no cost by the Department of Health to these programs, and recordkeeping and reporting are minimal.

### **Compliance Requirements:**

Under the proposed rule, eligible providers that elect to establish opioid overdose prevention programs will report overdose reversal on forms provided by the NYSDOH. Record keeping mandated of programs is minimal. The proposed amendments eliminate

one previously required element: the logging of specific trainings. The proposed regulations also eliminate the requirement that registered programs request a renewal of their active status every two years; the Department will commence the renewal process absent a specific request from the programs. No new requirements have been mandated. Offering of opioid overdose prevention programs is entirely voluntary.

**Professional Services:**

No additional professional services will be required since providers and others will be able to utilize existing staff or can utilize the services of others with whom they have a relationship.

**Compliance Costs:**

The additional organizations under the revised regulations that are eligible to operate opioid overdose prevention programs and that seek NYSDOH approval to establish these programs will be provided with application guidelines and technical assistance. The additional organizations are local government agencies, other than local health departments which were already eligible; institutions of higher education recognized and approved by the Regents of the University of the State of New York which provide a course of study leading to the granting of a post-secondary degree or diploma; and business, trade, technical or other occupation schools approved as such by the Regents of the University of the State of New York or accredited by a nationally recognized accrediting agency or association accepted as such by the Regents of the State of New York. Reporting requirements pertaining to opioid overdose prevention programs will be

minimal for those providers that voluntarily elect to establish such opioid overdose prevention programs. The estimated cost of reporting is, at most, \$150 per year.

**Economic and Technological Feasibility:**

Most health care facilities, health care practitioners, drug treatment programs, community-based organizations, educational institutions and local government agencies that are, or would be, eligible to offer opioid overdose prevention programs have the capacity and expertise to carry out the necessary activities. Small businesses that opt to voluntarily offer opioid overdose prevention programs will be provided with necessary forms and instructions to comply with the approval process and reporting requirements. In large part, these forms and instructions are developed with specific input from regulated parties and NYSDOH resources are being made available to provide instructions and technical assistance.

**Minimizing Adverse Impact:**

There are no alternatives to the proposed recordkeeping and reporting requirements due to the need for the NYSDOH to assure that approved opioid overdose prevention programs conduct activities in a manner to maximize impact and for purposes of providing information to the Governor and the Legislature in accordance with Section 3309(4) of the Public Health Law.

**Small Business and Local Government Participation:**

Small businesses (including small business hospitals, clinics, health care practitioners, drug treatment programs, individual practitioners, and community-based organizations) as well as local health departments had an opportunity to review and comment on the original regulations and a similar opportunity is being provided with respect to the changes in the regulations. The NYSDOH has already begun to have conversations with local government agencies and educational institutions interested in having opioid overdose prevention programs.

## RURAL AREA FLEXIBILITY ANALYSIS

### **Types and Estimated Number of Rural Areas:**

Rural areas are defined as counties with a population less than 200,000 and, for counties with a population greater than 200,000, includes towns with population densities of 150 persons or less per square mile. There are 43 counties in NYS with a population less than 200,000. Eleven counties have certain townships with population densities of 150 persons or less per square mile. The proposed rule will have minimal impact on hospitals, clinics, health care practitioners, drug treatment programs and local governments in these rural areas.

The additional organizations under the revised regulations that are eligible to operate opioid overdose prevention programs are local government agencies, other than local health departments which were already eligible; institutions of higher education recognized and approved by the Regents of the University of the State of New York which provide a course of study leading to the granting of a post-secondary degree or diploma; and business, trade, technical or other occupation schools approved as such by the Regents of the University of the State of New York or accredited by a nationally recognized accrediting agency or association accepted as such by the Regents of the State of New York. Registration as an opioid overdose prevention program is entirely voluntary. Potential providers are most likely to be located in urban or suburban, not rural, areas. For example, NYSDOH SPARCS data show 21,202 hospital discharges for admissions related to opioid overdose in 2008. Of these, 10,073 (48%) were in NYC.

Most of the admissions outside of NYC were in the urban regions of Syracuse, Rochester, Buffalo, Albany and Long Island. Similarly, OASAS county-level estimates of treatment need show that the greatest need for opioid overdose prevention programs is in urban and suburban areas (OASAS, 2004 County Resource Book, Volume I. Service Need and Utilization Data, Table 2).

**Reporting, Record Keeping and Other Compliance Requirements; and Professional Services:**

Under the proposed rule, reporting, record keeping and other compliance requirements applicable to providers that seek NYSDOH approval to offer opioid overdose prevention programs will be minimal. They will be limited to providing aggregate reports on forms and in formats provided by the NYSDOH. Providers may, on a voluntary basis, agree to collect and provide more detailed information for evaluation purposes.

**Costs:**

No new capital or annual costs of compliance are imposed by the rule. The costs incurred to implement opioid overdose prevention programs are anticipated to be minimal. In addition, the Department of Health will provide technical and other assistance.

**Minimizing Adverse Impact:**

The program is designed to minimize impact on those who will participate: participation

is voluntary, the approval process will be minimal, no fee will be charged, and record-keeping requirements will be minimal.

The new opioid overdose prevention programs will build upon already-existing programs and services for drug injectors, through hospitals, clinics, health care practitioners, drug treatment programs, community-based organizations and local health departments and human services agencies. The NYSDOH will maintain and make available a list of approved programs.

### **Rural Area Participation:**

The department has actively sought to engender increased opportunities for opioid overdose prevention, including in rural parts of the state. That has entailed one-on-one dialog with—and technical assistance provided to—eligible providers in the state’s rural counties. That focus will not change with the amended regulation; however there will be increased opportunities for implementation of the regulated programs in rural areas because new classes of organizations will be eligible: local government agencies, other than local health departments, which were already eligible; institutions of higher education recognized and approved by the Regents of the University of the State of New York which provide a course of study leading to the granting of a post-secondary degree or diploma; and business, trade, technical or other occupation schools approved as such by the Regents of the University of the State of New York or accredited by a nationally recognized accrediting agency or association accepted as such by the Regents of the State of New York.

The mechanisms for engaging rural participation include outreach by department staff, by the Harm Reduction Coalition, and by NYSDOH-approved syringe exchange programs.

The NYSDOH, since the implementation of the current regulations, has considered input on how they could be improved. The most significant changes in the proposed regulation, including expanded eligibility and reduced recordkeeping, were the product of this input.

## **JOB IMPACT STATEMENT**

A Job Impact Statement is not required. The proposed rule will not have a substantial adverse impact on jobs and employment opportunities based upon its nature, purpose and subject matter.