Opioid Overdose Programs

Effective: 5/6/15

SUMMARY OF EXPRESS TERMS

The regulatory changes accomplish the following:

- authorize clinical directors and affiliated prescribers to prescribe an opioid antagonist to trained overdose responders, and for those prescriptions to be either patient-specific or non-patient-specific;
- require clinical directors to designate those individuals by name or by description who will be furnishing or dispensing naloxone pursuant to a non-patient specific prescription;
- allow for trained overdose responders to have shared access to, and use of, an opioid antagonist so long as the following conditions are met: they are trained in accordance with the regulations; they have a common organizational or workforce bond; and there are policies and procedures in place within that organization or workforce that ensure orderly, controlled access to an opioid antagonist by an identifiable pool of trained overdose responders;
- expand the organizations which may have regulated opioid overdose prevention programs to include the following: public safety agencies, state agencies and pharmacies;
- add a reporting requirement, so that the department will know on a quarterly basis how many overdose responders each program trains as well as how many doses of naloxone each program furnishes;

- require public safety and firefighting personnel to have their overdose reversals reported directly to the department by their agencies;
- require the maintenance and provision of masks or other similar barriers only for those programs which incorporate rescue breathing in their curriculum;
- acknowledge the curriculum approved by the Division of Criminal Justice Services as acceptable for trained overdose responders who are public safety personnel, and acknowledge that a comparable curriculum approved by the Department of Health may be used for firefighters;
- require that registered programs maintain and furnish instructional material to participants, including how to recognize symptoms of an opioid overdose; the steps to be taken in responding to an opioid overdose; and how to access the Office of Alcoholism and Substance Abuse Services (OASAS) through both a toll-free number and its website;
- require that documentation be furnished at the time naloxone is dispensed pursuant to a non-patient specific prescription that indicates the following: that naloxone has been furnished pursuant to a non-patient specific prescription; the name of the prescriber; the opioid antagonist being prescribed; the date of the furnishing or dispensing; and the name of the person receiving the opioid antagonist; and
- acknowledge that prescribers unaffiliated with registered programs may issue patient-specific prescriptions for an opioid antagonist to individuals in their care at risk of an opioid overdose.

Pursuant to the authority vested in the Commissioner by Public Health Law Section 3309(1), section 80.138 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:

Section 80.138. Opioid overdose prevention programs.

(a) Definitions.

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

(2) Opioid antagonist means [an FDA-approved drug] a drug approved by the Food and Drug Administration, 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.

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

(4) Opioid overdose prevention training curriculum 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 and, where appropriate, providing resuscitation.

(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;

(v) a local health department, public safety agency, or other local or state 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[.]; and

(viii) a pharmacy registered in accordance with the Article 137 of the Education Law.

(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 individual or an identifiable pool of 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 individual or an identifiable pool of trained overdose responders.

(9) Trained overdose responder means any individual not otherwise permitted by law to administer an opioid antagonist, who is either:

(i) an opioid antagonist recipient as defined in PHL Section 3309 who has successfully completed an opioid overdose prevention training curriculum offered by an authorized opioid overdose prevention program [within the past two years] and has been authorized by a registered provider to possess the opioid antagonist;

(ii) a public safety officer who has completed a curriculum approved by the division of criminal justice services for purposes of intervening in opioid overdoses prior to the arrival of emergency medical services; or

(iii) a firefighter who has completed a comparable curriculum approved by the department.

(b) Registration.

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

(2) Providers eligible to register to operate an opioid overdose prevention program that are in good standing may apply to the department to operate an opioid overdose prevention 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;

(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;

(iv) the name, license type and license number of the affiliated prescribers, if any;

(v) the name and address of the sites at which the opioid overdose prevention program will be conducted; and

(vi) a description of the targeted population to be served and recruitment strategies to be employed by the opioid overdose prevention program.

(c) Program operation.

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

(i) identify a clinical director to oversee the clinical aspects of the opioid overdose prevention program;

(ii) establish the content of the program's opioid overdose prevention training curriculum consistent with guidance from 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 program's opioid overdose prevention training curriculum; however, certificates of completion of curriculum under subparagraphs (ii) and (iii) of paragraph (9) of subdivision (a) of this section are not required for public safety or firefighting personnel;

(vi) establish and maintain the opioid overdose prevention program's mandated recordkeeping system;

(vii) ensure that all trained overdose responders successfully complete 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 involving administration of an opioid antagonist; [and]

(x) report all administrations of an opioid antagonist on forms prescribed by the department; however, public safety and firefighting personnel are required to report administrations of an opioid antagonist directly, or through their department or agency, to the department[.]; and

(xi) report the number of trained overdose responders and the number of doses of an opioid antagonist provided on a quarterly basis on forms prescribed by the department.

(2) Each opioid overdose prevention program shall have a clinical director who is responsible for clinical oversight and liaison concerning medical issues related to the opioid overdose prevention 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 opioid overdose prevention program;

(iii) provide consultation to ensure that all trained overdose responders are properly trained;

(iv) adapt and approve opioid overdose prevention training curriculum content and protocols; [and]

(v) review reports of all administrations of an opioid antagonist[.]; and

(vi) designate individuals, either by name or by description, who are authorized to dispense or furnish an opioid antagonist to trained overdose responders and/or individuals who are responsible for ensuring orderly, controlled, shared access to an identifiable pool of trained overdose responders pursuant to a non-patient specific prescription.

(3) The trained overdose responders shall:

(i) complete an initial training consistent with the program's opioid overdose prevention training curriculum;

(ii) complete a refresher training consistent with the opioid overdose prevention training curriculum at least every two years or otherwise demonstrate competence in opioid overdose recognition and response to the satisfaction of the opioid overdose prevention program director or to someone designated by the program director;

(iii) [contact an] ensure that emergency medical service has been contacted when encountering a victim of a suspected drug overdose and advise responding emergency medical services personnel if an opioid antagonist 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, or, in the case of responders who are public safety or firefighting personnel, comply with policies developed by their local public safety agency or fire department; and

(v) report all responses to victims of suspected drug overdose to the opioid overdose prevention program director or to someone designated [staff] by the program director.

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

(5) The opioid overdose prevention 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] consistent with its policies and procedures; however, these supplies must include:

(i) a mask or other barrier where rescue breathing is part of the curriculum;

(ii) an agent to prepare skin before injection where an injectable form of an opioid antagonist is used; and

(iii) instructional material required by the department, including information on how to recognize symptoms of an opioid overdose; the steps to be taken in responding to

an overdose; and how to access the office of alcoholism and substance abuse services through both a toll free number and its website.

(6) The opioid overdose prevention program's recordkeeping system must include, at a minimum, the following elements:

(i) the names of trained overdose responders, the dates they were trained, and the dates they were furnished naloxone; however, where an opioid antagonist is furnished or dispensed by an opioid overdose prevention program pursuant to a non-patient specific prescription, the program must also maintain records on who has issued the non-patient specific prescription and which designated program staff have dispensed or furnished the opioid antagonist and/or are responsible for ensuring orderly, controlled, shared access to an identifiable pool of trained overdose responders;

(ii) program policies and procedures;

(iii) copy of the contract/agreement with the clinical director, if appropriate;

(iv) opioid antagonist administration usage reports and forms;

(v) documentation of review of administration of an opioid antagonist; and

(vi) an inventory of overdose response supplies.

(7) The opioid overdose prevention program will establish a procedure by which any administration of opioid antagonist to another individual by a trained overdose responder affiliated with an opioid overdose prevention 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.

(9) Pursuant to Public Health Law[,] section 3309(2), the purchase, acquisition, possession or use of an opioid antagonist by an opioid overdose prevention program or a trained overdose responder in accordance with this section [and the training provided by an authorized opioid overdose prevention program] shall not constitute the unlawful practice of a profession or other violation under title 8 of the Education Law or article 33 of the Public Health Law.

(10) Trained overdose responders may have shared access to, and use of, an opioid antagonist so long as the following conditions are met:

(i) they are trained in accordance with these regulations;

(ii) they have a common organizational or workforce bond; and

(iii) there are policies and procedures in place within that organization or workforce that ensure orderly, controlled access to an opioid antagonist by an identifiable pool of trained overdose responders.

(11) Clinical directors and affiliated prescribers of registered providers are authorized to direct the furnishing or dispensing of an opioid antagonist to trained overdose responders pursuant to a patient-specific prescription or a non-patient specific prescription.

(12) All dispensing or furnishing of an opioid antagonist pursuant to a non-patient-specific prescription shall be to individuals who have been trained in opioid overdose recognition and response and be accompanied by documentation indicating:

(i) that the opioid antagonist has been furnished pursuant to a non-patient specific prescription;

(ii) the name of the prescriber;

(iii) the opioid antagonist being prescribed;

(iv) the date of the dispensing or furnishing; and

(v) the name of the person (or identification of the pool under subparagraph (iii) of paragraph (10) of this subdivision) receiving the opioid antagonist.

(d) Nothing in this section shall prevent a health care practitioner from issuing a patient-specific prescription for an opioid antagonist as otherwise permitted by 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), as amended by Chapters 34 and 42 of the Laws of 2014, 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 opioid drug overdoses. To achieve this objective, the revised regulations address the issuance of non-patient specific prescriptions for an opioid antagonist, something that is permitted for the first time under the 2014 revisions to PHL Section 3309. The regulations also authorize a practice implicit in the statute: the shared access to—and use of—an opioid antagonist by trained overdose responders. To further address the law's objective of reducing the incidence of fatal overdoses, the regulations support a broader range of qualified organizations in becoming registered opioid overdose prevention programs by including public safety agencies, state agencies and pharmacies as eligible organizations. The law and the regulations also mandate that the furnishing or dispensing of naloxone be accompanied by information on recognizing the symptoms of an opioid overdose, on what steps to take

in the course of an overdose, on how to access the HOPE Line maintained by the Office of Alcoholism and Substance Abuse Services (OASAS); and on how to access the OASAS web site.

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

In 2013, there were 115,000 admissions to OASAS-certified treatment programs where heroin or other opioids was the primary, secondary, or tertiary substance of abuse. This was an increase of 23% from 88,000 such admissions in 2004.

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 may also include the administration of naloxone which immediately reverses the effects of an opioid 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 recommended for many years and is being offered in a variety of settings in a growing number of jurisdictions throughout the United States. 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 June 30, 2014,

more than 140 programs have registered as Overdose Prevention Providers and more than 75,000 naloxone kits have been distributed by NYSDOH. As of that same date, there were 918 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; 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) (208, 22.7%), Erie (175, 19.1%) and Bronx (157, 17.1%) counties.

The amendment to the rule achieves the following: 1) health care providers are authorized to issue patient specific and non-patient specific prescriptions for naloxone; 2) in instances when regulated programs will be using non-patient specific prescriptions for naloxone, the clinical director must delegate those individuals who will be carrying out the dispensing; 3) shared access to—and use of—naloxone among trained overdose responders is now permitted so long as: a) these responders are trained in accordance with the regulations; b) there is a common organizational or workforce bond among them; and c) there are policies and procedures in place within that organization or workforce that ensure orderly, controlled access to an opioid antagonist by an identifiable pool of trained overdose responders; 4) provider eligibility has been expanded to include public safety agencies, state government agencies and pharmacies; 5) registered programs will now be required to report on a quarterly basis the number of doses provided to trained overdose responders and the number of responders trained; and 6) all naloxone distribution is to be accompanied by information on how to recognize an opioid overdose,

how to respond to an opioid overdose; and how to access OASAS, both through its HOPE Line as well as through its web site.

These changes under the proposed regulations will result in improved distribution of naloxone in the community and result in reduced incidence of fatal opioid overdoses. The reporting requirement will give the state an improved understanding of the impact of this program. Expanded access to naloxone does not lead to increased drug use. Naloxone is not addictive and does not cause a "high." It has no potential for abuse, nor does it have a street value associated with diversion.

Costs:

There are no new mandates. This regulation continues to allow, not require, creation of opioid overdose prevention programs. Costs for the implementation and ongoing operations of regulated programs to those parties that elect to establish them will continue to be minimal. As was past practice, no registration fee is being collected. 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 regulated program's Program Director. Internal operational policies and procedures, as well as the training of staff, remain as requirements. Reporting requirements are minimal and consistent with Public Health Law.

The state has appropriated and is making funding available for the following activities. The NYSDOH estimates that approximately 48,000 individuals will become trained

overdose responders between April 1, 2014 and March 31, 2015 at an estimated annual cost of $3,000,000 for the kits. Training costs will be covered with existing resources within the Department of Health budget. The amount for subsequent years will decrease considerably, in part because of the accrued benefit of train-the-trainer sessions. The estimated annual cost in the years subsequent to the 2014-2015 State Fiscal Year is likely to range between $1,000,000 and $2,000,000. All of these costs are borne with State funding. There is no local funding used for this initiative.

Local Government Mandates:

For purposes of implementing amendments to Section 3309 of the Public Health Law, local government agencies will be made aware of the option to voluntarily offer opioid overdose prevention programs, though in no case is participation in this program mandated. 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 programs are minimal. 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. The principal goal of the regulatory changes is to ensure improved access to naloxone in the community by allowing non-patient specific prescriptions of naloxone and shared access to—and use of—naloxone by trained overdose responders under specified conditions. The proposed rule also allows for the following additional eligible providers to maintain regulated overdose programs: public safety agencies, state agencies and pharmacies. None of those entities would be required to maintain an overdose prevention program; rather they may voluntarily choose to have such a 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 continue to report overdose reversal on forms provided by the NYSDOH. There is an additional requirement mandating that the regulated programs report to the department on a quarterly basis the number of doses of naloxone provided to trained overdose responders as well as the number of responders trained. Record keeping mandated of programs is minimal.

Offering of opioid overdose prevention programs remains 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:

There are no additional costs associated with non-patient specific prescriptions for naloxone nor for the shared access to—and use of—naloxone. In fact, the shared access to naloxone may reduce the burden on organizations whose staff are being trained in opioid overdose.

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 public safety agencies, state agencies and pharmacies. 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 practitioners and organizations 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. NYSDOH has a responsibility to ensure that approved opioid overdose prevention programs conduct activities in a manner that maximizes the impact of this program. It also has a responsibility to collect information consistent with the reports to the Governor and the Legislature that are mandated in Section 3309(5) 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 as well as on subsequent proposed changes. A similar opportunity is being provided with respect to the changes in the regulations now being proposed, particularly with non-patient specific prescriptions for naloxone and shared access to—

and use of—naloxone by trained overdose responders. The department has already begun to have conversations with public safety agencies and some registered programs regarding these issues. There will also be discussions with pharmacies and state agencies that are now eligible to maintain registered 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, include 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 practitioners, organizations, local governments and pharmacies in these rural areas.

The additional organizations under the revised regulations that are eligible to operate opioid overdose prevention programs are public safety agencies, state government and pharmacies. In rural areas, those entities most likely to be represented among new registrants are public safety agencies and pharmacies. 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.

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

Under the proposed regulations, reporting, record keeping and other compliance requirements applicable to providers that seek department approval to offer opioid overdose prevention programs are minimal. There is a new reporting requirement that

registered programs on a quarterly basis inform the department of the number of doses of naloxone provided to trained overdose responders as well as the number of responders trained. These data are essential for the department to be compliant with mandated reports to the Governor and the Legislature.

Costs:

The department, either directly or under contract, will provide technical and other assistance to organizations and practitioners implementing opioid overdose prevention programs.

Minimizing Adverse Impact:

The program is designed to minimize impact on those who will participate in the following ways: participation is voluntary; the registration process is simple; no fees are charged; and record-keeping and reporting requirements are minimal.

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: public safety agencies, state agencies and pharmacies.

The mechanisms for engaging rural participation include outreach by department staff, as well as from local health departments and from staff from the Office of Alcoholism and Substance Abuse Services, the Division of Criminal Justice Services, the Harm Reduction Coalition, Albany Medical College and other community partners.

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 non-patient specific prescriptions; shared access to, and use of, naloxone by trained overdose responders; and expanded eligibility 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.

ASSESSMENT OF PUBLIC COMMENT

The Department received two comments on the Proposed Rule Making from currently registered opioid overdose prevention programs. The commenters asked whether clinical directors and affiliated prescribers of opioid overdose prevention programs may be subject to liability for prescribing opioid antagonists.

The Department interprets "opioid overdose prevention program" in Public Health Law § 3309(4) to include a clinical director or affiliated prescriber of such program. Thus, clinical directors and affiliated prescribers, acting reasonably and in good faith in compliance with Public Health Law § 3309, would not be subject to criminal, civil or administrative liability solely by reason of prescribing opioid antagonists or any other acts within the scope of 10 NYCRR § 80.138.