Pursuant to the authority vested in the Commissioner of Health by sections 2800, 2803, 2803-u, and 2999-cc of the Public Health Law, sections 400.21, 405.9, 405.19, and 405.20 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) are hereby amended and a new section 505.39 is added to Title 18 of the NYCRR, to be effective upon publication of a Notice of Adoption in the New York State Register:

Paragraph (1) of subdivision (b) of section 400.21 of Title 10 is amended to read as follows:

(1) An advance directive means a type of written or oral instruction relating to the provision of health care when an adult becomes incapacitated, including but not limited to a health care proxy, a consent to the issuance of an order not to resuscitate or other medical orders for life-sustaining treatment (MOLST) recorded in a patient's/resident's medical record, [and] a living will, and a voluntary non-opioid directive.

New paragraphs (7) and (8) are added to subdivision (b) of section 400.21 of Title 10 to read as follows:

(7) Opioid means an opiate, opium, an opium derivative, or a synthetic opioid which is listed on schedule II, III, IV, or V of section 3306 of the Public Health Law including an opiate, opium, an opium derivative, or a synthetic opioid contained in a narcotic drug listed on such schedules.

(8) Voluntary non-opioid directive means a written form executed by an adult evidencing such adult's request not to have an opioid offered, supplied, prescribed or otherwise administered to such adult by a health care practitioner, except where:

(i) the opioid is offered, prescribed, supplied or otherwise administered for the treatment of a substance use disorder; or

(ii) a health care practitioner acting in good faith determines it is medically necessary to override a voluntary non-opioid directive, provided that for an individual who has a documented substance use disorder or appears to have or be at risk for a substance use disorder, appropriate referrals shall be made to mitigate the likelihood of relapse.

Subparagraphs (i) and (ii) of paragraph (1) of subdivision (d) of section 400.21 of Title 10 are amended and a new subparagraph (iii) is added to read as follows:

(i) the description of State law prepared by the department entitled "Deciding About Health Care: A Guide for Patients and Families," which summarizes the rights, duties and requirements of Articles 29-C, 29-CC and 29-CCC; [and]

(ii) the pamphlet prepared by the department entitled "Health Care Proxy: Appointing your Health Care Agent in New York State," containing a sample health care proxy form; and

(iii) the pamphlet prepared by the Department, in consultation with the Office of Alcoholism and Substance Abuse Services, entitled “Non-Opioid Directive: A Guide for Patients and Families”;

Subdivisions (f) and (g) are relettered (g) and (h) and new subdivision (f) is added to section 405.9 of Title 10 to read as follows:

(f) Individuals with Substance Use Disorders. The hospital shall develop and maintain written policies and procedures for inpatient and outpatient care of individuals with documented substance use disorders or who appear to have or be at risk for substance use disorders, as that term is defined in section 1.03 of the Mental Hygiene Law.

(1) Such policies and procedures shall, at a minimum, meet the following requirements:

(i) Policies and procedures shall provide for the use of an evidence-based approach to identify and assess individuals for substance use disorders, and to refer individuals with documented substance use disorders or who appear to have or be at risk for substance use disorders;

(ii) Upon admission, treatment, or discharge of an individual with a documented substance use disorder or who appears to have or be at risk for a substance use disorder, including discharge or transfer from the emergency service of the hospital or assignment to observation services pursuant to paragraph (2) of subdivision (e) of section 405.19 of this Part, the hospital shall inform the individual of the availability of the substance use disorder treatment services that may

be available to him or her through a substance use disorder services program. Such information may be provided verbally and/or in writing as appropriate;

(iii) During discharge planning, the hospital shall provide to each individual with a documented substance use disorder or who appears to have or be at risk for a substance use disorder with educational materials, identified by the Office of Alcoholism and Substance Abuse Services in consultation with the Department and provided to the hospital pursuant to subdivision 1 of section 2803-u of the Public Health Law;

(iv) Except where an individual has come into the hospital under section 22.09 of the Mental Hygiene Law, and where the hospital does not directly provide substance use disorder services, the hospital shall refer individuals in need of substance use disorder services to and coordinate with appropriate substance use disorder services programs that provide behavioral health services, as defined in section 1.03 of the Mental Hygiene Law;

(v) The hospital shall establish and implement training, in addition to current training programs, for all individuals licensed or certified pursuant to title eight of the education law who provide direct patient care regarding the policies and procedures established in this paragraph; and

(vi) The requirements of this subdivision shall apply to all service units of the hospital;

(2) The hospital may use addiction professionals to provide, assist in the provision of, or refer individuals to substance use disorder services pursuant to paragraph (1) of this subdivision, in

consultation with the attending practitioner and consistent with the scope of the addiction professional's professional license or certification;

(i) Such addiction professionals shall be available on-site or by telehealth, as that term is defined by article 29-G of the Public Health Law, within thirty minutes of a request for services.

(ii) For purposes of this section, an "addiction professional" shall mean:

(*a*) a person who, acting within the scope of his or her license or certification issued pursuant to title 8 of the education law or credential issued pursuant to section 19.07 of the Mental Hygiene Law, provides substance use disorder services as that term is defined in section 1.03 of the Mental Hygiene Law;

(*b*) a peer advocate who provides peer support services pursuant to a national credential or other credential authorized by the Office of Alcoholism and Substance Abuse Services, provided that such services may be provided only on-site; or

(*c*) any other person, as attested to by the hospital, who has appropriate experience and/or training and meets such other qualifications as are established by such hospital, to provide or facilitate the provision of needed services as required pursuant to this paragraph;

New paragraph (5) is added to subdivision (c) of section 405.19 of Title 10 to read as follows and existing paragraphs (5) through (9) are renumbered (6) through (10):

(5) The emergency service shall provide for the use of an evidence-based approach to identify and assess individuals for substance use disorders, as that term is defined in section 1.03 of the Mental Hygiene Law, and described in subdivision (f) of section 405.9 of this Part.

Paragraph (4) of subdivision (c) of section 405.20 of Title 10 is amended, paragraph (5) is renumbered (6) and new paragraph (5) is added to read as follows:

(4) compliance with the domestic violence provisions of section 405.9(e) of this Part; [and]

(5) identification, assessment, and referral of individuals with documented substance use disorders or who appear to have or be at risk for substance use disorders, as that term is defined in section 1.03 of the Mental Hygiene Law, and described in subdivision (f) of section 405.9 of this Part; and

A new section 505.39 is added to Title 18 to read as follows:

505.39 Telehealth providers. Pursuant to paragraph (t) of subdivision (2) of section 2999-cc of the Public Health Law, the following are hereby defined as telehealth providers: credentialed alcoholism and substance abuse counselors credentialed by the Office of Alcoholism and Substance Abuse Services or by a credentialing entity approved by such office pursuant to section 19.07 of the Mental Hygiene Law.

SUMMARY OF REGULATORY IMPACT STATEMENT

This proposal represents a response to the prevalence of substance use disorders and particularly to the growing scope of the heroin and opioid crisis. Heroin overdose is now the leading cause of accidental death in the state and 2,028 New Yorkers died of a drug overdose in 2014. In 2015, approximately 107,300 New York residents received treatment for opioid substance use.[1] A number of state programs and initiatives have been developed, including the Department of Health (DOH) Prevention Agenda and the Delivery System Reform Incentive Payment (DSRIP) Program that have made great strides in addressing the needs of individuals with substance use disorders. Similarly, many hospitals have undertaken their own initiatives in this regard. Nevertheless, despite ongoing initiatives to address the prevalence of substance abuse, the scope of this serious public health situation continues to expand, impacting individuals, families and communities throughout New York State.

Public Health Law (PHL) section 2803-u(4) provides that the Commissioner of Health shall issue regulations as necessary to implement the provisions of the section, pertaining to general hospital policies and procedures related to the identification, assessment and referral of individuals with substance use disorders. This proposal adds new 10 NYCRR § 405.9(f) to require hospitals to develop and maintain written policies and procedures for the identification, assessment, and referral of individuals with substance use disorders. Among other things, the subdivision requires that the policies and procedures provide for the use of an evidence-based approach in identifying and assessing individuals with substance use disorders. The policies and procedures must also provide for the hospital to inform the individual of the availability of the

[1] *Heroin and Opioid Task Force Report,* June 9, 2016, "Combatting the Heroin and Opioid Crisis," available at https://www.governor.ny.gov/sites/governor.ny.gov/files/atoms/files/HeroinTaskForceReport_3.pdf, , p. 2.

substance use disorder treatment services that may be available through a substance use disorder services program. Further, the hospital must train appropriate staff in such policies and procedures.

In carrying out the assessment and referral requirements, the hospital may use "addiction professionals," who would have to be available on-site or by telehealth, as that term is defined by Public Health Law Article 29-G, within thirty minutes of a request for services. An "addiction professional" is defined as a person who is: (1) a person licensed or certified under Education Law Title 8 or credentialed under Mental Hygiene Law § 19.07; (2) a peer advocate (who would have to provide services on-site rather than by telehealth); or (3) any other individual identified by the hospital with appropriate experience and/or training. The proposal adds a new 18 NYCRR § 505.39 to identify Credentialed Alcoholism and Substance Abuse Counselors (CASACs) as "telehealth providers" who can provide services via telehealth.

This proposal also adds new 10 NYCRR § 405.19(c)(5) to incorporate into the section the provisions outlined above related to hospital policies and procedures for the identification, assessment and referral of individuals with substance use disorder. Similarly, a new 10 NYCRR § 405.20(c)(5) incorporates the provisions outlined above related to hospital policies and procedures for the identification, assessment and referral of individuals with substance use disorder.

It may be helpful for hospitals carrying out these requirements to be aware of new services and programs that have recently been established or are in the process of being developed. For example, the AIDS Institute within DOH has created a pilot program for Health Hubs which, among other things, work directly with emergency departments at local hospitals so that individuals who are released from the emergency department have access to additional

services. The Office of Alcoholism and Substance Abuse Services (OASAS), has established an on-line Treatment Availability Dashboard, found at https://findaddictiontreatment.ny.gov, which can be used to search for state certified outpatient or bedded programs. OASAS also has several projects underway which seek to establish peer programs in each of the State's ten economic development regions.

In addition, this proposal also amends 10 NYCRR § 400.21(b) to include a "voluntary non-opioid directive" as a type of advance directive. A voluntary non-opioid directive is defined as a written form executed by an adult to evidence the individual's request not to have an opioid offered, supplied, prescribed or administered to the named adult by a health care practitioner, except for the treatment of a substance use disorder. A health care practitioner acting in good faith may override a voluntary non-opioid directive form if medically necessary, but in such case an individual with a substance use disorder must be provided with appropriate referrals to mitigate the likelihood of relapse. To effectuate these provisions, DOH, in consultation with OASAS, will issue a pamphlet entitled "Non-Opioid Directive: A Guide for Patients and Families."

While the current regulations do not specifically refer to individuals with substance use disorders, hospitals are already required to establish written policies and procedures related to various operational requirements, train staff in such policies and procedures and refer patients to appropriate follow-up care. The proposed regulations provide that in carrying out the new provisions related to the identification, assessment and referral of individuals with substance use disorders, hospitals may elect to hire additional staff to serve as addiction professionals or contract with others to provide such services, but also can use telehealth or rely upon existing

staff with appropriate training or expertise. This flexibility should help minimize any costs associated with such arrangements.

There are no alternatives to the proposed regulations related to hospital policies and procedures, which are consistent with PHL § 2803-u, added by Chapter 70 of the Laws of 2016. DOH could forego establishing the voluntary non-opioid directive form, but would miss an opportunity to help individuals promote their recovery in a time where heroin and opioid use is at crisis levels. Further, it is not clear that there are any alternatives which would achieve the same objectives while being consistent with the advance directive provisions of PHL Article 29-C and 29-CC.

Contact Person: Katherine Ceroalo
New York State Department of Health
Bureau of House Counsel, Regulatory Affairs Unit
Corning Tower Building, Room 2438
Empire State Plaza
Albany, New York 12237
(518) 473-7488
(518) 473-2019 (FAX)
REGSQNA@health.ny.gov

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) § 2803 authorizes the Public Health and Health Planning Council (PHHPC) to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of PHL Article 28, and to establish minimum standards governing the operation of health care facilities."

PHL § 2803-u(4) provides that the Department of Health (DOH), in conjunction with the Office of Alcoholism and Substance Abuse Services (OASAS), shall issue regulations as necessary to implement the provisions of the section, which requires general hospitals to establish and train staff in policies and procedures for the identification, assessment and referral of individuals with substance use disorders.

PHL Article 29-G provides that services provided via telehealth must be reimbursed under Medicaid to the same extent as if they were provided in a face-to-face interaction, if they meet certain criteria. PHL § 2999-cc(2)(t) authorizes the Commissioner of Health to add additional providers to the list of "telehealth providers" by regulation.

Legislative Objectives:

This proposal will implement PHL § 2803-u, added by Chapter 70 of the Laws of 2016, requiring general hospitals to establish policies and procedures for the identification, assessment and referral of individuals with substance use disorders and to train staff in those policies and procedures. In particular, the statute provides for hospitals to refer individuals in need of substance use disorder services to appropriate programs and coordinate with such programs. As described herein, these requirements were enacted as part of a multi-pronged approach to

addressing the prevalence of substance use disorder and particularly the heroin and opioid addiction problem that has grown to crisis levels in communities throughout New York State.

As outlined below, one way in which hospitals can carry out these requirements is by relying upon "addiction professionals" that in some cases can provide such services by means of telehealth. Under PHL Article 29-G, to be eligible for Medicaid reimbursement, services provided from a "distant site" must be provided by a "telehealth provider." PHL § 2999-cc(2) lists "telehealth providers" including physicians, physician assistants, nurse practitioners, and social workers, and authorizes the Commissioner of Health to identify additional "telehealth providers" by regulation. Consistent with that authority, this proposal will identify as "telehealth providers" Credentialed Alcoholism and Substance Abuse Counselors (CASACs), who are credentialed by OASAS or an entity approved by OASAS pursuant to Mental Hygiene Law (MHL) § 19.07. This will allow CASACs, who are generally located at clinics operated or certified by OASAS, to provide "addiction professional" services via telehealth, helping hospitals carry out the objectives of PHL § 2803-u.

This proposal also establishes a "voluntary non-opioid directive" as a form of advance directive recognized under 10 NYCRR § 400.21, to be used by individuals interested in expressing their desire not to be offered or provided with opioids by health care practitioners. As noted within that section, New York's Health Care Proxy Law and the Family Health Care Decisions Act (PHL Articles 29-C and 29-CC, respectively), reflect the right of individuals to make decisions about their health care through another adult. Advance directives permit such individuals to express preferences about their health care, including a desire to continue or to refuse treatment. Identifying a "voluntary non-opioid directive" as a form of advance directive

will allow individuals with substance use disorder to support their recovery by expressing their wish to avoid opioids.

Current Requirements:

General hospitals are required by section 405.9 of Title 10 of the New York Compilation of Codes, Rules and Regulations of New York (NYCRR) to refer patients for appropriate follow-up care after discharge from the hospital. Similar provisions are set forth in 10 NYCRR §§ 405.19 and 405.20 pertaining to hospital emergency and outpatient services. However, the current regulations do not specifically reference individuals with substance use disorders.

Needs and Benefits:

In New York State, approximately 1.4 million New Yorkers suffer from a substance use disorder.[2] OASAS is the state agency responsible for certifying or authorizing providers and administers various prevention, treatment, and recovery programs that seek to address this issue. However, DOH also undertakes a variety of efforts in this regard. For example, substance use disorder is one of the elements highlighted in the DOH Prevention Agenda, an initiative through which local health departments, health care providers, health plans, and community based organizations collaborate to improve population health. Moreover, DOH's Health Homes program provides comprehensive case management for Medicaid enrollees with complex medical, behavioral, and long term care needs that drive a high volume of high cost services.

[2] *Heroin and Opioid Task Force Report,* June 9, 2016, "Combatting the Heroin and Opioid Crisis," available at https://www.governor.ny.gov/sites/governor.ny.gov/files/atoms/files/HeroinTaskForceReport_3.pdf, , p. 2.

This population includes individuals whose co-occurring conditions include substance use disorder.

Further, substance use disorder is an area of focus under the Delivery System Reform Incentive Payment (DSRIP) Program. DSRIP is a major component of the Medicaid waiver agreement approved by the federal Centers for Medicare and Medicaid Services ("CMS") in 2014 that allowed New York State to reinvest $8 billion of Medicaid savings generated as a result of MRT initiatives over a five-year period. DSRIP promotes community-level collaborations and focuses on system reform, with the specific goal of achieving a 25 percent reduction in avoidable hospital use over five years. Providers have come together to form 25 Performing Provider Systems (PPS) to collaborate on innovative projects focusing on system transformation, clinical improvement and population health improvement. One project available to and selected by every PPS, known as DSRIP Project 3.a.i, seeks to promote the integration of primary and behavioral care. Project 4.a.ii, chosen by several PPS, focuses specifically on preventing substance abuse. Moreover, all PPS are focused on reducing avoidable hospitalizations and as part of that work a specific focus on patients with substance use disorder including opiate use has been undertaken by a variety of DSRIP quality improvement teams.

Hospitals are already serving as partners in responding to the opioid and heroin crisis, and many have implemented innovative programs, often in conjunction with DSRIP projects. One example is the Staten Island PPS, which provides access to a variety of data including local overdose poisonings, overdose deaths and inpatient and emergency department admissions attributable to substance use disorder. The PPS has implemented a program to connect patients with peers and provide a "warm handoff" to needed substance use disorder services and resources upon discharge. A second example, albeit one that is not part of a DSRIP project, is

the State University of New York Upstate Emergency Opioid Bridge clinic. This model engages patients in the emergency department to participate in a buprenorphine program. The patient is immediately connected to a clinic at the hospital for follow up care. That clinic ensures patients are seen by a Peer Connector to arrange long term substance use disorder treatment services. Collectively, efforts by state agencies and health care providers have been successful in developing initiatives to help New Yorkers in dealing with substance use disorder.

Nevertheless, the prevalence of substance use disorders has continued to increase. Moreover, the number of people affected in particular by opioid and heroin addiction has grown so dramatically over the last several years that it constitutes a public health crisis, impacting thousands of people and their families throughout New York State communities.[3] Heroin overdose is now the leading cause of accidental death in the state and 2,028 New Yorkers died of a drug overdose in 2014.[4] In 2015, approximately 107,300 New York residents received treatment for opioid substance use.[5]

To identify ways to combat this issue, the Governor convened the Heroin and Opioid Task Force. The Task Force issued a report setting forth a series of recommendations, many of which were included in Governor's Program Bills Nos. 31, 32, and 33 of 2016. Subsequently, the Governor signed Chapters 69, 70 and 71 of the Laws of 2016, which included several initiatives to address heroin and opioid abuse across the state. Among other things, the new laws include measures to increase access to overdose reversal medication, limit opioid prescriptions

[3] Id. at p. 2.
[4] Id. at p. 2.
[4] Id. at p. 10.

for acute pain from 30 to 7 days, require ongoing education on addiction and pain management for prescribers, and eliminate insurance barriers for treatment and medication.

Of particular relevance is new PHL § 2803-u, added by Chapter 70 of the Laws of 2016. As noted in the sponsor's memorandum, individuals who present at emergency rooms for treatment of an opioid overdose often are "simply stabilized and released, without the provision of treatment information or additional follow-up. However, continuous access to appropriate treatment and services is critical for an individual to have any chance to overcome an addiction." Accordingly, PHL § 2803-u requires general hospitals to establish policies and procedures and train staff in the identification, assessment and referral of individuals with or who appear to be at risk for substance use disorders.

Specifically, subdivision 1 of the new statute requires OASAS, in consultation with DOH, to develop new or identify existing educational materials for general hospitals to disseminate to individuals who have or appear to have substance use disorders as part of discharge planning. The materials will include information such as: (1) the various types of treatment and recovery services such as inpatient, outpatient, and medication-assisted treatment; (2) how to recognize the need for treatment services; and (3) information for individuals to determine what type and level of treatment is most appropriate and what resources are available to them.

New PHL § 2803-u(2)(a) requires hospitals to develop, maintain and disseminate written policies and procedures for the identification and assessment and referral of individuals with documented substance use disorders or who appear to have or be at risk for substance use disorders. New PHL § 2803-u(2)(b) requires hospitals to train their licensed and certified clinical staff members who provide direct patient care in such policies and procedures. Under

new PHL § 2803-u(2)(c), hospitals must refer individuals in need of substance use disorder services to appropriate programs and coordinate with such programs. New PHL § 2803-u(3) provides that hospitals must inform individuals with documented substance use disorders or who appear to have or be at risk for substance abuse disorders of the availability of treatment services that may be available through a substance use disorder services program. Finally, new PHL § 2803-u(4) provides that the Commissioner of Health, in consultation with the Commissioner of OASAS, shall issue regulations as necessary to carry out the new section.

To build upon existing efforts and consistent with the foregoing legislative requirements, this proposed regulation will require general hospitals to: (1) provide individuals who have or appear to have substance use disorders with educational materials, to be developed by OASAS in consultation with DOH, as part of discharge planning; (2) establish written policies and procedures for the identification and assessment (using an evidence-based approach) as well as the referral of individuals who have or appear to have substance use disorders; (3) train licensed and certified staff in such policies and procedures; (4) refer individuals in need of substance use disorder services to appropriate programs and coordinate with such programs; (5) inform individuals who have or appear to have substance use disorders of treatment services that may be available, which can be accomplished verbally and/or in writing as appropriate; and (6) clarify that hospitals may meet the foregoing requirements by using "addiction professionals." Further, the proposed regulation clarifies that "telehealth providers" include CASACs credentialed under MHL § 19.07, which will expand the options available to hospitals in using "addiction professionals" located at OASAS clinics.

Specifically, the proposed regulation clarifies that hospitals may meet the foregoing requirements by using an "addiction professional" to provide or facilitate the provision of

substance use disorder services, as long as the professional is able to arrive at the hospital or be available by telehealth within 30 minutes of a request. An "addiction professional" is defined as a person who is: (1) licensed or certified under Education Law Title 8 or credentialed by OASAS under MHL § 19.07 to provide substance use disorder services; (2) a certified recovery peer advocate who holds a certification approved by OASAS for purposes of providing peer support services, provided that such services may be provided only on-site; or (3) identified by the hospital as someone with experience and/or training qualifying him or her to assist in providing or facilitating the provision of substance use disorder services.

Under this language, hospitals would be able to directly employ qualified individuals or otherwise arrange for the availability of such individuals, including through telehealth modalities. Among the options for such arrangements via telehealth are practitioners such as physicians, physician assistants, nurse practitioners or social workers, who are currently listed as "telehealth providers" under PHL 2999-cc. This proposal would add CASACs to that list. It should be noted that CASACs generally are employed by providers operated or certified by OASAS and are not authorized to practice independently or seek Medicaid reimbursement. A claim for Medicaid reimbursement of an engagement or counseling session that occurs via telehealth would have to be billed by the clinic employing the CASAC rather than the CASAC itself.

Hospitals also would be able to utilize peer support services provided by certified recovery peer advocates pursuant to an OASAS approved certification, although those services could not be delivered via telehealth. Finally, hospitals would be able to identify persons who are qualified due to their experience and/or training to provide or facilitate the provision of needed substance use disorder services.

As noted above, the proposed regulation requires the identification and assessment of individuals with substance use disorders by using any approach that is evidence-based. One such evidence-based approach is the Screening, Brief Intervention and Referral to Treatment (SBIRT). SBIRT seeks to identify patients who use alcohol and other drugs at risky levels with the goal of reducing and preventing related health consequences, disease, accidents and injuries. Risky substance use is a health issue and often goes undetected. Information on SBIRT is available on the OASAS website at http://www.oasas.ny.gov/adMed/sbirt/index.cfm, which includes a video introducing this approach.

Consistent with the statute, the regulation requires hospitals to refer individuals in need of substance use disorder services to appropriate programs and "coordinate" with such programs, which can be carried out by an addiction professional. Coordination, at a minimum, requires a referral to the most appropriate level of care but as appropriate should also include activities such as securing admission to an on-site substance use disorder services program or making an appointment with a program in the community, or establishing a telehealth connection with a distant addiction professional who can further engage with the individual to identify needed services.

In carrying out these requirements, hospitals should be aware of the OASAS Treatment Availability Dashboard, found at https://findaddictiontreatment.ny.gov, which can be used to search for state certified outpatient or bedded programs. The dashboard also links (https://www.oasas.ny.gov/hps/state/CD_descriptions.cfm) to a description of the levels of care within each of the major service categories of substance use disorder treatment services (crisis, inpatient, outpatient, opioid treatment and residential). This tool will help hospitals identify

programs that exist within their communities and to which they can connect individuals with substance use disorders.

It may also be helpful for hospitals to be aware of new types of services that have been developed and are expanding throughout the State to assist people in need of substance use disorder services. For example, in 2016, the AIDS Institute within DOH created a pilot program with four harm reduction agencies to become Health Hubs. The hubs mobilize communities around drug user health in their regions and provide services including buprenorphine, aftercare and safety plans to prevent future overdoses, medical care including hepatitis C treatment, health screening, and alternatives to incarceration. The Health Hubs work directly with emergency departments at local hospitals so that individuals who are released from the emergency department have access to additional services. Additional Health Hubs will be developed in the near future.

In addition, as announced by the Governor earlier this year, a grant administered by OASAS supported the opening of the first "Open Access Center." The Next Step Resource and Recovery Center in Staten Island, operated by Community Health Action of Staten Island (which is also one of the pilot providers under the AIDS Institute's Health Hubs program) will be open seven days per week, 24 hours per day, for the purpose of providing access to services and information for people in recovery from substance use disorders as well as their families. A similar center recently opened in Monroe County, and additional Open Access Centers will be developed.

In addition, over the course of the last year, OASAS has launched a Peer Engagement Specialist program, which supports the availability of individuals who are in recovery or who have personal experience with family members in recovery in a variety of settings to provide

support, encouragement and guidance in finding appropriate services. OASAS has also initiated a Family Support Navigator program, designed to assist families and individuals in understanding how addiction progresses and guide them in accessing treatment services. These programs will be expanded, with the ultimate goal of establishing two Peer Engagement Specialist programs and two Family Support Navigator programs in each of the state's ten economic development regions.

These resources all should prove to be of significant value for hospitals seeking to connect patients with substance use services in their communities. It is worth emphasizing, however, that the State's response to the heroin and opioid crisis includes not only new programs and services to promote recovery, but also includes a variety of initiatives that also focus on prevention. For example, OASAS has received a grant from the federal Substance Abuse and Mental Health Services Administration (SAMHSA) for funding under the State Targeted Response to the Opioid Crisis Grants (Opioid STR) authorized by the 21st Century Cures Act. This grant will provide a total of $25 million over five years which will be used in part to support the development of peer programs for hard-to-reach youth in each of the State's ten economic development regions.

In addition to the foregoing, this proposal provides for a "voluntary non-opioid directive" for use by individuals who wish to avoid being offered or provided with opioids by to health care practitioners, other than for the treatment of a substance use disorder. Such directives, which would be categorized as a type of advance directive under the regulations, could be used by individuals with substance use disorders as a tool to support their recovery or by individuals aware of the potentially addictive effects of opioids who prefer to avoid their use. In such cases, as necessary, the use of other pain management medications or techniques would be explored.

As reflected in the proposed regulation, DOH, in consultation with OASAS, would issue a pamphlet including a standard form for the voluntary non-opioid directive. It should be noted that unlike the other provisions of the proposal, which primarily are addressed to general hospitals, a voluntary non-opioid directive would be available to individuals regardless of setting. Accordingly, as is the case with the other pamphlets referenced in the existing regulation on advance directives, 10 NYCRR § 400.21, the pamphlet would be distributed by providers in general hospitals as well as nursing homes. Further, both agencies would make such pamphlet and form available on their websites for use by individuals interested in pursuing that option.

In sum, the growing availability of community resources should assist hospitals in building upon their ongoing efforts to deal with the impact of the heroin and opioid crisis by connecting people with services as envisioned by Chapter 70 and the regulation. Further, the development of a voluntary non-opioid directive will provide individuals with an option to aid in their own recovery, also helping address the epidemic of heroin and opioid use.

COSTS:

Costs to Private Regulated Parties:

While the current regulations do not specifically refer to individuals with substance use disorders, hospitals are already required to have written policies and procedures related to various operational requirements, train staff in such policies and procedures and refer patients to appropriate follow-up care. The proposed regulations do require additional effort to ensure that the policies and training encompasses the identification, assessment and referral of individuals with substance use disorder, as well as the provision of information related to substance use disorder services, consistent with the requirements of the statute. The regulations seek to afford

hospitals some flexibility in how these requirements are met. For example, while hospitals may elect to hire additional staff to serve as addiction professionals or contract with others to provide such services, they may also use telehealth or rely upon existing staff with appropriate training or expertise, which should help minimize any costs associated with such arrangements.

Costs to Local Government:

This proposal will not impact local governments unless they operate a general hospital, in which case the impact would be the same as outlined above for private parties.

Costs to the Department of Health:

Because the proposal is likely to lead to additional telehealth encounters, it could lead to additional costs for DOH associated with: (1) the 50 percent state share of Medicaid reimbursement for clinic engagement or counseling encounters prompted by hospital referrals; and (2) the 50 percent state share of the administrative fee paid by Medicaid for each telehealth encounter, amounting to $25 provided to the "originating site" (the hospital) and $25 to the "distant site" (where the "telehealth provider" is located).

Because telehealth is only one means of meeting the regulatory requirements, it is unknown how many encounters will occur and therefore difficult to estimate such costs. In any event, however, the expectation that in many of these cases the connection to substance use disorder services will occur in lieu of other clinic encounters and may avert the necessity for more expensive emergency department care in the future.

The proposed regulatory changes will not result in any additional operational costs to DOH, as the new requirements will be incorporated into existing surveillance activities. The

development of the educational materials to be distributed to individuals with substance use disorder during discharge planning as well as the pamphlet for the voluntary non-opioid directive, both to be developed in conjunction with OASAS, is expected to be managed within existing resources.

Costs to Other State Agencies:

The proposed regulatory changes will not result in any additional costs to other state agencies. OASAS, in consultation with DOH, will develop or utilize existing educational materials to be distributed to individuals with substance use disorders as part of the discharge planning process, as well as assist DOH in developing the pamphlet for the voluntary non-opioid directive, which is expected to be managed within existing resources.

Local Government Mandate:

The proposed regulations do not impose any new programs, services, duties or responsibilities upon any county, city, town, village, school district, fire district or other special district.

Paperwork:

General hospitals are already required to establish written policies and procedures related to various operational requirements, train staff in such policies and procedures, and refer patients to appropriate follow-up care. Therefore, the proposed regulations should not significantly increase their paperwork.

Duplication:

While existing regulations require hospitals to make appropriate referrals, those regulations do not specifically reference individuals with substance use disorders. There otherwise are no relevant State regulations which duplicate, overlap or conflict with the proposed regulations.

Alternatives:

There are no alternatives to the proposed regulations related to hospital policies and procedures, which are consistent with PHL § 2803-u, added by Chapter 70 of the Laws of 2016. DOH could forego establishing the voluntary non-opioid directive form, but would miss an opportunity to help individuals promote their recovery in a time where heroin and opioid use is at crisis levels. Further, it is not clear that there are any alternatives which would achieve the same objectives while being consistent with the advance directive provisions of PHL Article 29-C and 29-CC.

Federal Standards:

The proposed regulations do not duplicate or conflict with any federal regulations.

Compliance Schedule:

The regulations will be effective upon publication of a Notice of Adoption in the New York State Register.

Contact Person: Katherine Ceroalo
New York State Department of Health

Bureau of House Counsel, Regulatory Affairs Unit
Corning Tower Building, Room 2438
Empire State Plaza
Albany, New York 12237
(518) 473-7488
(518) 473-2019 (FAX)
REGSQNA@health.ny.gov

REGULATORY FLEXIBILITY ANALYSIS
FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect of Rule:

The proposed regulatory provisions related to substance use disorders will apply to all general hospitals in New York State. This proposal will not impact local governments or small business unless they operate a general hospital. In such case, the flexibility afforded by the regulations is expected to minimize any costs of compliance as described below.

Compliance Requirements:

These regulations will require general hospitals to develop, maintain and disseminate written policies and procedures for the identification and assessment (using an evidence-based approach) as well as the referral of individuals with documented substance use disorders or who appear to have or be at risk for substance use disorders. Hospitals will be required to train their licensed and certified clinical staff members in such policies and procedures. The use of the voluntary non-opioid directive, which would not be limited to hospital settings, will be similar to other advance directives.

Professional Services:

While the current regulations do not specifically refer to individuals with substance use disorders, hospitals are already required to establish written policies and procedures related to various operational requirements, train staff in such policies and procedures and refer patients to appropriate follow-up care. The proposed regulations provide that in carrying out the provisions related to the identification, assessment and referral of individuals with substance use disorders,

hospitals may elect to hire additional staff to serve as addiction professionals or contract with others to provide such services, but also can use telehealth or rely upon existing staff with appropriate training or expertise. This flexibility should help minimize any costs associated with such arrangements.

Compliance Costs:

While the current regulations do not specifically refer to individuals with substance use disorders, hospitals are already required to establish written policies and procedures related to various operational requirements, train staff in such policies and procedures and refer patients to appropriate follow-up care. The proposed regulations do require additional effort to ensure that the policies and training encompasses the identification, assessment and referral of individuals with substance use disorder, as well as the provision of information related to substance use disorder services, consistent with the requirements of the statute. The regulation seeks to afford hospitals some flexibility in how these requirements are met. For example, while hospitals may elect to hire additional staff to serve as addiction professionals or contract with others to provide such services, they may also use telehealth or rely upon existing staff with appropriate training or expertise, which should help minimize any costs associated with such arrangements.

Economic and Technological Feasibility:

This proposal is economically and technically feasible. While existing regulations do not specifically refer to individuals with substance use disorders, hospitals are already required to establish written policies and procedures related to various operational requirements, train staff in such policies and procedures and refer patients to appropriate follow-up care. To carry out the

requirements of the regulations, hospitals may elect to hire additional staff to serve as addiction professionals or contract with others to provide such services, but the regulation permits additional flexibility, including the use of telehealth.

Minimizing Adverse Impact:

There are no alternatives to the proposed regulations related to hospital policies and procedures, which are consistent with PHL § 2803-u, added by Chapter 70 of the Laws of 2016. The Department of Health could forego establishing the voluntary non-opioid directive form, but would miss an opportunity to help individuals promote their recovery in a time where heroin and opioid use is at crisis levels. Further, it is not clear that there are any alternatives which would achieve the same objectives while being consistent with the advance directive provisions of PHL Article 29-C and 29-CC.

Small Business and Local Government Participation:

Development of these regulations included input from organizations including those whose members include general hospitals that are operated by local governments or that constitute small businesses.

Cure Period:

Chapter 524 of the Laws of 2011 requires agencies to include a "cure period" or other opportunity for ameliorative action to prevent the imposition of penalties on a party subject to enforcement when developing a regulation or explain in the Regulatory Flexibility Analysis why

one is not included. As this proposed regulation does not create a new penalty or sanction, no cure period is necessary.

RURAL AREA FLEXIBILITY ANALYSIS

Types and Estimated Numbers of Rural Areas:

This rule applies uniformly throughout the state, including rural areas. Rural areas are defined as counties with a population less than 200,000 and counties with a population of 200,000 or greater that have towns with population densities of 150 persons or fewer per square mile. The following 43 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2010 (http://quickfacts.census.gov). Approximately 17% of small health care facilities are located in rural areas.

Allegany County
Cattaraugus County
Cayuga County
Chautauqua County
Chemung County
Chenango County
Clinton County
Columbia County
Cortland County
Delaware County
Essex County
Franklin County
Fulton County
Genesee County
Greene County
Hamilton County
Herkimer County
Jefferson County
Lewis County
Livingston County
Madison County
Montgomery County
Ontario County
Orleans County
Oswego County
Otsego County
Putnam County
Rensselaer County
Schenectady County
Schoharie County
Schuyler County
Seneca County
St. Lawrence County
Steuben County
Sullivan County
Tioga County
Tompkins County
Ulster County
Warren County
Washington County
Wayne County
Wyoming County
Yates County

The following counties have a population of 200,000 or greater and towns with population densities of 150 persons or fewer per square mile. Data is based upon the United States Census estimated county populations for 2010.

Albany County
Broome County
Dutchess County
Erie County
Monroe County
Niagara County
Oneida County
Onondaga County
Orange County
Saratoga County
Suffolk County

There are 47 general hospitals, approximately 90 diagnostic and treatment centers, 159 nursing homes, and 92 certified home health agencies in rural areas.

Reporting, Recordkeeping, Other Compliance Requirements and Professional Services:

The proposed regulation is applicable to those general hospitals located in rural areas and is expected to impose only minimal costs upon hospitals, which are already required to establish written policies and procedures related to various operational requirements, train staff in such policies and procedures and refer patients to appropriate follow-up care. Because the proposed regulatory requirements can be incorporated into existing processes, they are not expected to substantially increase the administrative burden on these entities.

Costs:

The proposed changes are expected to impose only minimal costs upon general hospitals and diagnostic and treatment centers, which are already required to establish written policies and procedures related to various operational requirements, train staff in such policies and procedures and refer patients to appropriate follow-up care.

Minimizing Adverse Impact:

There are no alternatives to the proposed regulation. The proposed regulations are consistent with PHL § 2803-u, added by Chapter 70 of the Laws of 2016 to require general hospitals to establish policies and procedures pertaining to individuals with substance use disorders.

Rural Area Participation:

Development of these regulations included input from organizations including those that include as members general hospitals located in rural areas.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

No job impact statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. No adverse impact on jobs and employment opportunities is expected as a result of these proposed regulations.