Pursuant to the authority vested in the Commissioner of Health by sections 2803 and 2803-u(4) of the Public Health Law, sections 405.9, 405.18, 405.19, 405.20 and 407.5 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) are hereby amended, to be effective upon publication of a Notice of Adoption in the New York State Register:

Subparagraph (ii) of paragraph (11) of subdivision (b) of section 405.9 of Title 10 is amended to read as follows:

(ii) If a patient eligible for transfer to a hospital operated by the Veteran's Administration requests such transfer, hospital staff shall make such arrangements. Transfer shall be effected in accordance with paragraph [(f)(7)] (g)(7) of this section.

Subdivision (f) is relettered as (g) and a 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. Such policies and procedures shall, at a minimum, meet the following requirements:

(1) 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;

(2) 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;

(3) 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;

(4) 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; and

(5) 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.

Subdivision (g) of section 405.9 of Title 10 is relettered as (h) and subparagraph (ii) of paragraph (7) of the former subdivision (f), now relettered as subdivision (g), of section 405.9 of Title 10 is amended to read as follows:

(ii) Patients discharged from the hospital by their attending practitioner shall not be permitted to remain in the hospital without the consent of the chief executive officer of the hospital except in accordance with provisions of subdivision [(g)] (h) of this section.

Subparagraph (vi) of paragraph (2) of subdivision (b) of section 405.18 of Title 10 is amended to read as follows:

(vi) In accordance with the provisions of section [405.9(f)] 405.9(g) of this Part, rehabilitation therapy staff shall work with the attending practitioner, the nursing staff, other health care providers and agencies as well as the patient and the family, to the extent possible, to assure that all appropriate discharge planning arrangements have been made prior to discharge to meet the patient's identified needs.

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 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, as 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 a 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, as described in subdivision (f) of section 405.9 of this Part; and

Paragraph (6) of subdivision (b) of section 407.5 of Title 10 is amended to read as follows:

(6) Discharge/transfer. Hospitals shall comply with the provisions of paragraph (1) of subdivision [(g)] (h) of section 405.9 of this Title concerning discharge/transfer. In addition, PCHs and CAHs shall comply with the following:

* * *

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 consultation 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.

Legislative Objectives:

Chapter 70 of the Laws of 2016 enacted Public Health Law (PHL) § 2803-u as part of a multi-pronged approach to address the prevalence of substance use, particularly heroin and opioids, that has become a serious public health crisis impacting communities throughout New York State. PHL § 2803-u requires general hospitals to establish policies and procedures for the identification, assessment and referral of individuals with or at risk of 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. This proposal will implement these requirements as described below.

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.[1] 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.[2] 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.[3] In 2015, approximately 107,300 New York residents received treatment for opioid substance use.[4]

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

[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.

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

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 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.

As part of this approach, new PHL § 2803-u was 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, PHL § 2803-u(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.

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. 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 PHL § 2803-u(2)(c), hospitals must refer individuals in need of substance use disorder services to appropriate programs and coordinate with such programs. 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 use disorders of the availability of treatment services that may be available through a substance use disorder services program. Finally, 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.

Consistent with these 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; and (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.

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 regulations require hospitals to refer individuals in need of substance use disorder services to appropriate programs and "coordinate" with such programs. 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 practitioner who can further engage with the individual to identify needed services.

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 disorders, as well as the provision of information related to substance use disorder services, consistent with the requirements of the statute. However, these efforts are expected to assist individuals in obtaining treatment that will help them avoid future emergency room visits and hospital admissions.

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:

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 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 educational materials to be distributed to individuals with substance use disorders as part of the discharge planning process, 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.

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.

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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.

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.

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. However, these efforts are expected to assist individuals in obtaining treatment that will help them avoid future emergency room visits and hospital admissions.

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.

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.

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:

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. However, these efforts are expected to assist individuals in obtaining treatment that will help them avoid future emergency room visits and hospital admissions.

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.