Public Health and Health Planning Council

Codes, Regulations and Legislation Committee Meeting
Agenda and Informational Announcements

August 3, 2017
10:15 AM

Location: Meeting Room 6, Concourse, Empire State Plaza, Albany, New York

A. Agenda

For Adoption	**Program Area**	**Unit Representative**
Amendments to Section 710.1 of Title 10 NYCRR – Certificate of Need Review Thresholds	Office of Primary Care and Health Systems Management	Lisa Ullman
Addition of Part 350 to Title 10 NYCRR – All Payer Database	Office of Quality and Patient Safety	Mary Beth Conroy

For Emergency Adoption	**Program Area**	**Unit Representative**
Amendments to Parts 400 and 405 of Title 10 NYCRR – Hospital Policies for Individuals with Substance Use Disorders	Office of Primary Care and Health Systems Management	Lisa Ullman

For Discussion	**Program Area**	**Unit Representative**
Amendments to Parts 400 and 405 of Title 10 NYCRR – Hospital Policies for Individuals with Substance Use Disorders	Office of Primary Care and Health Systems Management	Lisa Ullman

B. Information Announcements

1. Anyone wishing to make oral comments at this meeting should contact the Bureau of Policy and Standards Development by 11:00 A.M. on Wednesday, August 2, at 518-402-5914 to arrange for placement on the speakers' list. Please give your name, affiliation, if any and the agenda item(s) you wish to address. To ensure that all commenters have an opportunity to address the Committee, speakers should limit their comments to 3-4 minutes maximum.

2. All meeting attendees including Committee members are requested to sign the Attendance Sheet, which will be circulated in the meeting room.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by section 2816 and section 206(18-a)(d) of the Public Health Law, Part 350 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is added, to be effective upon publication of a Notice of Adoption in the New York State Register, provided that section 350.2 shall be effective January 1, 2018, to read as follows:

A new Part 350 is added to read as follows:

Part 350

All Payer Database (APD)

Sec.

§ 350.1 Definitions. For the purposes of this Part, these terms shall have the following meanings:

(a) "All Payer Database" or "APD" means the health care database maintained by the Department or its contractor that contains APD data.

(b) "APD data" means covered person data, claims data, and any other such data contained within standard transactions for Electronic Data Interchange (EDI) of

health care data adopted by the X12 standards organization, the National Council for Prescription Drug Programs (NCPDP) standards organization, any other organizations designated by the federal Department and Human Services to develop and maintain standard transactions for EDI of health care data, as provided in section 1320d-2 of Title 42 of the United States Code (USC) or any other federal law, or any other format designated by the Department for the collection of such data.

(c) "claims data" means:

(1) Benefits and coverage data – data specifying the benefits and coverage available to a covered person, such as cost-sharing provisions and coverage limitations and exceptions;

(2) Health care provider network data – data related to the health care provider and service networks associated with third-party health care payer plans and products, such as the services offered, panel size, licensing/certification, National Provider Identifier(s), demographics, locations, accessibility, office hours, languages spoken, and contact information;

(3) Post-adjudicated claims data – data related to health care claims, including payment data, that has been adjudicated by a third-party health care payer, such as the data included in the X12 Post Adjudicated Claims Data Reporting and the NCPDP Post Adjudication Standard transactions; and

(4) Other health care payment data, such as value based payment information, as determined by the Department.

(d) "covered person" means a person covered under a third-party health care payer contract, agreement, or arrangement that is licensed to operate in New York State by the New York State Department of Financial Services.

(e) "covered person data" means data related to covered persons, such as demographics, member identifiers, coverage periods, policy numbers, plan identifiers, premium amounts, and selected primary care providers.

(f) "data user" means any individual or organization that the Department has granted access to APD data, with or without identifying data elements.

(g) "health care provider" means a provider of "medical and other health services" as defined in 42 USC § 1395x(s), a "provider of services" as defined in 42 USC § 1395x(u), and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business. This includes a clinical laboratory, a pharmacy, an entity that is an integrated organization of health care providers, and an accountable care organization described in 42 USC § 1395jjj. The term also includes atypical providers that furnish nontraditional services that are indirectly health care-related, such as personal care, taxi, home and vehicle modifications, habilitation, and respite services.

(h) "identifying data elements" means those APD data elements that, if disclosed without restrictions on use or re-disclosure, would constitute an unwarranted invasion of personal privacy consistent with federal and state standards for de-identification of protected health information.

(i) "New York State agency" means any New York State department, board, bureau, division, commission, committee, public authority, public benefit corporation,

council, office, or other governmental entity performing a governmental or proprietary function for the State of New York.

(j) "submission specifications" means specifications determined by the Department for submitting covered person data and claims data to the APD, such as the data fields, circumstances, format, time, and method of reporting.

(k) "third-party health care payer" means an insurer, organization, or corporation licensed or certified pursuant to article thirty-two, forty-three, or forty-seven of the Insurance Law or article forty-four of the Public Health Law; or an entity, such as a pharmacy benefits manager, fiscal administrator, or administrative services provider that participates in the administration of a third-party health care payer system, including any health plan under 42 USC § 1320d. Unless permitted by federal law, the term does not include self-insured health plans regulated by the Employee Retirement Income Security Act of 1974, 29 USC Chapter 18, although such plans that operate in New York State may choose to participate as a third-party health care payer.

§ 350.2 APD data submission.

(a) Third-party health care payers shall submit complete, accurate, and timely APD data to the Department, pursuant to the submission specifications.

(b) The Department shall consult with the Department of Financial Services and third-party health care payers before issuing any submission specifications.

(c) The Department shall set a compliance date of at least 120 days from the date that new or revised submission specifications are issued.

(d) Third-party health care payers shall submit APD data in an electronic, computer-readable format through a secure electronic network of the Department or its

designated administrator on a monthly basis, or more frequently, as specified in the submission specifications.

(e) Third-party health care payers shall submit at least 95 percent of APD data within 60 days from the end of the month that the adjudicated claims were paid.

(f) Third-party health care payers shall submit 100 percent of APD data within 180 days from the end of the month of the adjudicated claims being submitted for payment.

(g) The Department may audit APD data submitted by third-party health care payers to evaluate the quality, timeliness, and completeness of the data. The Department may issue an audit report or statement of deficiencies listing any inadequacies or inconsistencies in the APD data submitted and requiring corrective actions. Any third-party health care payer that receives an audit report or statement of deficiencies shall submit a plan of correction to the Department within 30 days from the date of receipt of the audit report or statement of deficiencies. Third-party heath care payers shall be in full compliance with APD data submission specifications and the plan of correction within 90 days from the date of submission of the plan of correction.

(h) A third-party health care payer may submit a written request to the Department for an extension, variance, or waiver of APD data submission specifications requirements. The written request shall include: the specific requirement to be extended, varied, or waived; an explanation of the reason or cause; the methodology proposed to eliminate the need for future extension, variance, or waiver; and the time frame required to come into compliance. The Department shall respond to such requests as soon as practicable.

(i) Any third-party health care payer that violates this section shall be liable pursuant to the provisions of the Public Health Law, including, but not limited to, sections 12 and 12-d of the Public Health Law, and applicable sections of New York State Insurance Law and regulations.

§ 350.3 APD data release.

(a) The Department shall implement quality control and validation processes to provide reasonable assurance that APD data released to the public is complete, accurate, and valid. The Department shall adhere to applicable State and federal laws, regulations, and policies on release of Medicare and Medicaid data.

(b) Upon reasonable assurance that subdivision (a) has been satisfied, the Department may release data in the following manner:

(1) De-identified and/or aggregated APD data of a public use nature may be posted to a consumer-facing website.

(2) APD data, including data with identifying data elements, may be released to a New York State agency or the federal government in a manner that appropriately safeguards the privacy, confidentiality, and security of the data.

(3) APD data, including data with identifying data elements, may be released to other data users that have met the Department's requirements for maintaining security, privacy, and confidentiality and have approved data use agreements with the Department.

(c) Data users shall adhere to security, confidentiality, and privacy guidelines established by the Department to prevent breaches or unauthorized disclosures of

personal information resulting from any data analysis or re-disclosure. Data users bear full responsibility for breaches or unauthorized disclosures of personal information resulting from use of APD data.

(d) (1) Where the Department grants data users access to APD data that does not include identifying data elements, such access shall be subject to terms and conditions established by the Department.

(2) Data users who wish to request APD data that includes identifying data elements shall submit an application for a proposed project in a form established by the Department, which shall include an explicit plan for preventing breaches or unauthorized disclosures of identifying data elements of any individual who is a subject of the information. The Department's review of the proposed project shall include, but not be limited to: (i) use of the specific identifying data elements; (ii) adherence to the Department's guidance on the appropriate and controlled release of data; and (iii) assurance on whether the release of identifying data elements reflects overall goals of confidentiality, privacy, security, and benefits to public and population health.

(e) Any data user that violates this section or any data use agreement executed under this section shall be liable pursuant to the provisions of the Public Health Law, including, but not limited to, sections 12 and 12-d of the Public Health Law.

(f) The Department may charge reasonable fees for access to APD data, which shall be based upon estimated costs incurred and recurring for data processing, operation of the platform/data center, and software. The Department shall establish a

policy describing any APD data that shall be available at no charge, the fees for access to APD data subject to charge, the process for fee payment, and under what circumstances fees may be reduced or waived.

§ 350.4 APD advisory group.

(a) The Department may establish an advisory group to provide recommendations on any or all of the following areas: submission specifications, patient privacy and confidentiality, data release, data aggregation, and security.

(b) The Department may accept, reject, or amend recommendations, in whole or in part, from the advisory group.

§ 350.5 APD guidance.

The Department shall make guidance available on its website that includes:

(a) APD submissions specifications, including the data standards used and the method for reporting to the Department. Submission specifications shall be developed with a goal of minimizing burden on health care providers and third-party health care payers, including utilization of nationally standardized file formats where available and feasible.

(b) APD data access and release policy, including security and usage requirements to become a data user; requirements for maintaining privacy, confidentiality, and security; and data release fee information. Data access and release requirements shall include restrictions on the release of any information that could be used, alone or in combination with other reasonably available information, to identify an individual who is a subject of the information, as well as procedures for request of

identifying data elements, including the project application process established pursuant to subdivision (d) of section 350.3 of this Part.

(c) Program operations policy, including program purpose, scope and objectives, and general governance.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) § 2816 establishes the Statewide Planning and Research Cooperative System (SPARCS), which authorizes the New York State Department of Health to collect certain data relating to health care delivery in New York State. In particular, the statute authorizes the Department to collect data relating to insurance claims by persons covered by third-party insurers (hereinafter referred to as "payers"). The statute further provides: "Any component or components of the system may be operated under a different name or names, and may be structured as separate systems."

Accordingly, PHL § 2816 authorizes NYSDOH to collect covered person data and claims data in its All Payer Database (APD). Additionally, under PHL § 206(18-a)(d), the Commissioner of Health has the authority to "make such rules and regulations" on statewide health information systems, such as the APD, as recommended by the Health Information Technology Workgroup established pursuant to PHL § 206(18-a)(b)(ii).

Legislative Objectives:

In 2011, PHL § 2816 was amended specifically to authorize NYSDOH to develop and implement an All Payer Database for New York State. The Legislature further authorized NYSDOH to develop regulations establishing the necessary parameters, guidance, and requirements for a functional APD. These regulations are critical to the

successful collection and use of covered person data and claims data from commercial health care payers, which have previously not been done in New York State.

Needs and Benefits:

Currently, New York State has fragmented, inconsistent, and incomplete information about how the state's health care system is performing. With an array of state agencies and offices carrying out health care planning, along with a myriad of private efforts, data currently collected are specific to the goals of the distinct organization and sub-populations served.

This approach is administratively inefficient and costly, as it requires the redundant collection, cleansing, and storage of duplicative information. The lack of linkages and interoperability of data assets hinders the ability of health care and policy experts to fully assess issues, such as the impact of disease burden and treatment trends, the ability to inform policy on innovative payment and care coordination models, and other targeted interventions.

Advancing health care transformation in New York State requires a broad view of population health and system performance, which current data resources do not permit. States that currently have All Payer Claims Databases (APCDs) have proven that they are important tools for filling gaps in health care information. By streamlining health care system data processing, an APD will enable policymakers to monitor efforts to reduce health care costs and improve population health.

The APD will provide a robust dataset that will support a variety of comparative analyses. Further, the APD will transform New York State's health care system by

evaluating care delivery and payment models, and identifying opportunities to avoid waste, over/under utilization, misuse of treatments, and conflicting plans of care.

The APD will also yield findings that can be used to inform health care and finance decisions for policy makers, payers, providers, and consumers. For example, the APD will facilitate assessments of health care resource needs. APD data can also be used to effectively plan for and improve disease prevention, and to help ensure effective diagnosis, treatment, and rehabilitation services. APD data will allow the State to establish policies for risk adjustment, including mandatory risk adjustment calculations under the Federal Patient Protection and Affordable Care Act. In addition, the APD will enhance and expedite the ability of health payers and regulators to prescribe and determine appropriateness of premium rates.

Costs:

Costs to Regulated Parties:

Many health care insurance payers are already required to submit claims and records of care encounters to New York State. These include payers that have plans included in Medicaid Managed Care and in the New York State of Health Official Health Plan Marketplace (NYSoH), both of which require data submission as part of contractual agreements to participate in their respective programs. In addition, many payers voluntarily participate with private regional claims database initiatives, or submit data to other state APCDs.

Many of these public insurance program participants are also payers of commercial insurance plans, which lack access to claims history, and which have no

other mechanisms to mandate data submission. As a result, many of the payers participate in both public and private programs that involve some form of data submission.

For this reason, much of the staffing and information technology (IT) infrastructure required for mandatory participation in New York State's APD is already in place. There may be some initial increased implementation costs for payers who only participate in the private commercial market. Payers that currently report data in a proprietary format may also be exposed to costs associated with transitioning to a national standardized reporting format. However, because so much of the IT infrastructure is already in place, it is anticipated that regulated parties' long term costs associated with a fully functional APD will be minimal.

Costs to the NYSDOH:

As referenced in the prior section, many health care insurance payers are already required to submit claims and records of care encounters to New York State. While there is some infrastructure currently in place within NYSDOH, there is still a NYSDOH cost for the design, development, and implementation of infrastructure to operate the APD.

Costs include major system components of data intake, data warehousing, and data analytics, with a current estimate of $55 million for a three and a half-year development period. Following this development, the annual recurring operating costs for the system is estimated to be $20 million, inclusive of annual recurring NYSDOH staff costs of approximately $2 million. Total costs are covered by a combination of State appropriations, federal matching Medicaid and Child Health Plus funds, and federal Health Benefit Exchange grants.

Other systems in the NYSDOH, and the expenditures required to maintain them, will be partially reduced as the APD will assume some of the functions associated with them.

Costs to State and Local Governments:

There are no anticipated costs to local governments, as the APD will be fully developed and administered at the State level. There are minimal costs that may be incurred by the NYS Department of Financial Services to utilize the data and tools of the APD in the regulation of the commercial health insurance industry. These are not expected to be significant, however, and will be offset by the utility achieved through analysis of health insurance claims data.

Local Government Mandates:

The All Payer Database will be administered at the New York State level. This rule imposes no mandates upon any county, city, town, village, school district, fire district, or other special district.

Paperwork:

Payers will be required to submit registration forms and paperwork to NYSDOH or its designated administrator in order to submit claims data with protected information to the State. This paperwork is only required for initial registration with the APD, and subsequent communication is handled electronically. For this reason, the reporting requirements, forms, or other paperwork upon regulated parties are not expected to be a significant burden.

Duplication:

There are no relevant rules or other legal requirements of the federal or State governments that duplicate, overlap, or conflict with this rule.

Alternatives:

There are no alternatives that could serve as a substitute for the All Payer Database. Although New York State currently collects Medicaid and NYSoH data, the collection of commercial claims data is unprecedented. The APD is a significant new initiative that will allow for a comprehensive and valuable analysis of the health care system in New York State.

Federal Standards:

The rule does not exceed any minimum standards of the federal government for the same or similar subject area as the federal government does not operate an All Payer Database.

Compliance Schedule:

Development of the APD data intake component is being executed in a phased manner. The first phase included NYSoH Qualified Health Plans, and data collection began in January 2015. The second phase encompasses Medicaid and Child Health Plus Managed Care Plans, which went into production September 2015.

The third phase addresses third-party health care payers and the design and development process has already begun. This information is critical to the success of the APD. It is expected that production will begin for commercial payers in early 2018, with substantial attention to testing and user support to ensure all payers have the necessary tools to successfully participate.

Accordingly, section 350.2, which requires submission of data to the APD, does not take effect until January 1, 2018. In the event that the Department does not have the infrastructure in place to accept submissions from third-party health care payers by this date, the Department will issue guidance indicating the anticipated implementation and compliance date.

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STATEMENT IN LIEU OF

REGULATORY FLEXIBILITY ANALYSIS

No regulatory flexibility analysis is required pursuant to section 202-b(3)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on small businesses or local governments and it does not impose reporting, record keeping, or other compliance requirements on small businesses or local governments.

STATEMENT IN LIEU OF RURAL AREA FLEXIBILITY ANALYSIS

A Rural Area Flexibility Analysis for these amendments is not being submitted because amendments will not impose any adverse impact or significant reporting, record keeping, or other compliance requirements on public or private entities in rural areas. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

JOB IMPACT STATEMENT

Nature of Impact:

The rule will have minimal impact on jobs and employment opportunities. The regulated payers are largely established. In many cases, they are national health insurance companies that have an existing and deep data reporting infrastructure per the nature of the industry.

Many payers already report certain claims data to NYS and, with the APD, will now be required to send a higher volume. There may be some increase in hiring and jobs to ensure compliance with APD requirements; however, this impact is not expected to be significant. Much of the infrastructure already exists and many payers already submit data to public health insurance programs, regional voluntary databases, and other state APCDs. There will be some impact on employment in the IT contracting field as there will be contracts with NYSDOH to design, develop, implement, and operate the APD at the state level, as well as potential IT development work with some of the payers. There are no anticipated job impacts in any other segments or sectors of the job market. With regard to adverse employment effects, there is no expectation of job losses as a result of the rule.

Categories and Numbers Affected:

The types of jobs impacted by the rule are in the areas of IT and data analysis. The number of expected job additions is not specifically known but is expected to be minimal as payers have much of the existing resources needed to comply with data submission requirements. Most new work on the part of payers will be in the initial stages

of implementation. Payers that do not currently submit data to NYS will need to establish processes and set up IT systems to submit claims data.

Certain payers will have some level of system modification to comply with national standards and submission specifications. Some payers will utilize contract vendors for these activities who may already be familiar with the required transaction and buildout processes. IT contractors at the state level will see a short term increase for the design, development, and implementation of the system build, but ongoing operations support will rely on less staffing.

Regions of Adverse Impact:

There is no expectation of adverse impact on jobs in any region of NYS as a result of the rule.

Minimizing Adverse Impact:

There is no expectation of adverse impact on jobs in any region of NYS as a result of the rule.

Self-Employment Opportunities:

There is no expectation of any self-employment opportunities.

Pursuant to the authority vested in the Public Health and Health Planning Council, subject to the approval of the Commissioner of Health, by section 2803(2)(a) of the Public Health Law, section 710.1 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York is hereby amended, to be effective after publication of Notice of Adoption in the New York State Register, to read as follows:

Paragraph (3) of subdivision (b) of section 710.1 is amended to read as follows:

(3) [Reserved.] <u>For purposes of this Part, "general hospital" means a general hospital as defined in subdivision 10 of section 2801 of the public health law.</u>

Subparagraph (iii) of paragraph (1) of subdivision (c) of section 710.1 is amended to read as follows:

(iii) the initial acquisition or addition of any equipment, regardless of cost, utilized in the provision of a service listed in paragraph (2) of this subdivision, other than the acquisition or addition of equipment subject to paragraph ([7]<u>6</u>) of this subdivision. A proposal for the replacement of existing equipment, regardless of cost, which meets the criteria contained therein, shall not require an application but shall be processed pursuant to [subparagraph]<u>paragraph (4)[(iii)]</u>of this subdivision;

Subparagraph (vi) of paragraph (1) of subdivision (c) of section 710.1 is amended to read as follows:

(vi) any other construction, addition or replacement proposal involving a total project cost in excess of $15,000,000 for a general hospital or $6,000,000 for all other facilities, except non-clinical and health information technology projects subject to paragraph [5](4) of this subdivision.

Subclause (3) of clause (b) of subparagraph (i) of paragraph (2) of subdivision (c) of section 710.1 is amended to read as follows:

(3) cardiac catheterization, including the relocation of any Cardiac Catheterization Laboratory Center service within a network or to another site in a multi-site facility, as defined in Section 401.1 of this Title, and the addition of a PCI Capable Cardiac Catheterization Laboratory Center at a facility that is not already approved to provide cardiac catheterization services; provided however that the addition of a PCI Capable Cardiac Catheterization Laboratory Center or Cardiac EP Laboratory Program at a facility approved to provide cardiac catheterization services shall be reviewed pursuant to paragraph (3) of this subdivision, and the addition of a Cardiac EP Laboratory Program services at a facility approved to provide cardiac surgery shall be reviewed pursuant to paragraph ([7]6) of this subdivision;

Clause (c) of subparagraph (i) of paragraph (2) of subdivision (c) of section 710.1 is amended to read as follows:

(c) any proposal involving total project cost in excess of $30,000,000 for a general hospital or $15,000,000 for all other facilities, except as otherwise provided under paragraph (3) of this subdivision;

Clause (a) of subparagraph (ii) of paragraph (2) of subdivision (c) of section 710.1 is amended to read as follows:

(a) The addition of equipment utilized in the provision of Cardiac Catheterization Laboratory Center services shall be eligible for limited review pursuant to paragraph ([7]6) of this subdivision, to the extent that it does not otherwise require an administrative or a full review under this Part;

The opening paragraph of subparagraph (i) of paragraph (3) of subdivision (c) of section 710.1 is amended to read as follows:

(i) [Except as otherwise stated in this paragraph, the]The commissioner may administratively approve applications submitted pursuant to Article 28 of the Public Health Law and this Part [but] without the recommendation of the [State Hospital Review]Public Health and Health

Planning Council[,] when an application has not been recommended for [approval]disapproval by the health systems agency having jurisdiction, and where the total project cost does not exceed $30,000,000 for a general hospital or $15,000,000 for all other facilities. An application shall be eligible for administrative review even though total project costs exceed $30,000,000 for a general hospital or $15,000,000 for all other facilities, if: (a) total project costs do not exceed 10% of the total operating costs of the facility for the fiscal year ended two years prior to the submission of the application; and (b) total project costs do not exceed [$50,000,000;]$100,000,000 for a general hospital [as defined in section 2801 of the Public Health Law]or $25,000,000 for all other facilities. Notwithstanding anything in this Part to the contrary, any cost increase of a project in excess of $30,000,000 for general hospitals or $15,000,000 for all other facilities that is administratively reviewed under the subparagraph, resulting in total project costs in excess of the [$50,000,000]$100,000,000 for general hospitals or $25,000,000 for all other facilities, or in excess of 10% of the total operating costs of the facility for the fiscal year ended two years prior to the submission of the application, shall subject the application to full review. The following types of proposals are eligible for administrative review:

* * *

Clause (f) of subparagraph (i) of paragraph (3) of subdivision (c) of section 710.1 is amended to read as follows:

(f) [in] the addition, updating or modification of equipment utilized in the provision of a service listed in paragraph (2) of this subdivision, by a medical facility already approved to provide such service, except for the addition of equipment utilized in cardiac catheterization laboratory center services by a facility already approved to provide such service, which shall be subject to limited review pursuant to paragraph ([7]6) of this subdivision;

Clause (q) of subparagraph (i) of paragraph (3) of subdivision (c) of section 710.1 is amended to read as follows:

(q) [any proposal that relates to health information technology, provided that proposals with a total cost of up to $15 million may be reviewed under paragraph (5) of this subdivision]Reserved;

Subclause (7) of clause (w) of subparagraph (i) of paragraph (3) of subdivision (c) of section 710.1 is amended to read as follows:

(7) neither the facility nor any part thereof, nor the project is currently or is proposed to be financed by bonds or other debt instruments insured, enhanced or guaranteed by any state or municipal agency or public benefit corporation. Notwithstanding anything in this Part to the contrary, any cost increase of a primary care services project resulting in total project costs in excess of the $30,000,000 threshold for general hospitals or the $15,000,000 threshold for all

other facilities shall subject the application or amendment, as the case may be, to full review.

Clause (e) of subparagraph (i) of paragraph (4) of subdivision (c) of section 710.1 is amended to read as follows:

(e) Subject to clause (d) of subparagraph (ii) of paragraph 5 of this subdivision, any proposal for a nonclinical infrastructure project with total project costs in excess of $6,000,000 [, regardless of cost], including but not limited to replacement of heating, ventilating and air conditioning, fire alarm and call bell systems or components thereof, roofs, elevators, parking lots and garages, dietary, and solid waste and/or sewage disposal and upgrades of the exterior building envelope. The facility's written notice to the department shall include a written certification by a New York State licensed architect or engineer that the project meets the applicable statutes, codes and regulations; and shall include a plan to protect patient safety during construction consistent with section 711.2 of this part and other applicable standards, and as otherwise required by the department. Upon completion of the project, the facility shall, where applicable, submit written certification by a New York State licensed architect, engineer and/or physicist that the project as constructed or installed meets applicable statutes, codes and regulations; and such other close-out documents as may be specified by the department.

A new clause (g) is added to subparagraph (i) of paragraph (4) of subdivision (c) of section 710.1 to read as follows:

(g) Any proposal that relates to health information technology regardless of cost. For health information technology proposals involving the implementation of clinical information systems, electronic medical records, computerized physician order entry, radiology systems, lab ordering systems or other health information systems impacting patient care, the facility's written notice to the department shall include a certification of the technology's interoperability with other systems and conformance with state and federal guidelines and regulations governing the use and exchange of information, including privacy and security, that is acceptable to the department.

A new subparagraph (ii) is added to paragraph (4) of subdivision (c) of section 710.1 to read as follows:

(ii) Proposals for a nonclinical infrastructure project, including but not limited to replacement of heating, ventilating and air conditioning, fire alarm and call bell systems or components thereof, roofs, elevators, parking lots and garages, dietary, and solid waste and/or sewage disposal and upgrades of the exterior building envelope, where total project costs do not exceed $6,000,000, shall not require prior approval or written notice to the department under this Part, except as required by clause (d) of subparagraph (ii) of paragraph (5) of this subdivision.

The opening sentence of paragraph (5) of subdivision (c) of section 710.1 is amended to read as follows:

(5) Proposals requiring a limited review. Proposals where total project cost does not exceed $15,000,000 for a general hospital or $6,000,000 for all other facilities, and for which a certificate of need is not otherwise required under this Part, shall be reviewed under this paragraph, except for proposals covered by paragraph (4) of this subdivision.

Clause (g) of subparagraph (iv) of paragraph (5) of subdivision (c) of section 710.1 is amended to read as follows:

[(g) Any proposal to acquire, install or modify health information technology; provided that, notwithstanding any inconsistent provision in this paragraph, the cost of the proposal does not exceed $15 million. The applicant shall submit information, as requested by the department, including information concerning the technology's interoperability with other systems and conformance with state and federal guidelines and regulations governing the use and exchange of information, including privacy and security]Reserved.

Clause (b) of subparagraph (ii) of paragraph (6) of subdivision (c) of section 710.1 is amended to read as follows:

(b) Requests for approval of proposals described in this subparagraph shall be made [directly to the Director of the Division of Health Facility Planning. The applicant shall submit three (3)

copies of such request] through the electronic application submission process at the address posted on the department's website or any other means approved by the department, including information indicating the services to be provided, the facility areas to be utilized, and such other information as the Department may require. If construction is required, the request should include the cost of such construction and other information required by the Bureau of Architectural and Engineering Facility Planning under this Part. If the proposal involves the addition of Cardiac EP Laboratory Program Services, the applicant shall also submit a copy to the local health systems agency (HSA) having jurisdiction, if any. The HSA shall have 10 days to make a recommendation to the department.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) section 2803(2)(a) provides that the Public Health and Health Planning Council (PHHPC) shall adopt rules and regulations, subject to the approval of the Commissioner of Health, to effectuate the purposes of PHL Article 28 with respect to hospitals.

Legislative Objectives:

PHL section 2800 declares that "[h]ospital and related services including health-related service of the highest quality, efficiently provided and properly utilized at a reasonable cost, are of vital concern to the public health" and bestows upon the Department of Health the "central, comprehensive responsibility for the development and administration of the state's policy with respect to hospital and related services."

The review of applications for hospital establishment and construction is referred to as the Certificate of Need (CON) process, the objectives of which are to align health care resources with community health needs, preserve and promote access to high quality health care, and control utilization to promote cost-effective health care.

PHL section 2801-a provides that hospitals, defined in PHL section 2801 to mean "general hospitals", nursing homes and diagnostic and treatment centers, may not be established except as approved by PHHPC. PHHPC may not approve establishment unless it is satisfied as to the public need for and financial feasibility of the proposed project, the character and competence of the proposed owners and operators, and such other matters as it deems pertinent.

The construction of a hospital, defined by PHL section 2801 to mean the erection,

building, or substantial acquisition, alteration, reconstruction, improvement, extension or modification of a hospital, including its equipment, requires the prior approval of the Commissioner under PHL section 2802. The Commissioner may approve a construction application only after affording PHHPC an opportunity to make a recommendation, except where regulations adopted by PHHPC and approved by the Commissioner provide that PHHPC review is not necessary, and only if the Commissioner is satisfied as to public need, financial feasibility and character and competence.

PHL section 2802 details procedures for approval of hospital construction projects and provides that certain types of hospital construction projects require written notice to the Department but not prior approval. These include the acquisition of minor equipment, non-clinical infrastructure projects (such as replacement of heating, ventilating and air conditioning systems, parking lots and elevators), the replacement of existing equipment, and other projects set forth in regulation.

Current Requirements:

Consistent with these provisions, Department regulations establish the parameters of the CON process for establishment and construction projects. Part 600, *et seq.*, of Title 10 of the Official Compilation of New York Codes, Rules and Regulations (NYCRR) pertains to establishment and 10 NYCRR Part 710, *et seq.*, relates to construction projects.

Part 710 of 10 NYCRR, *et seq.*, defines three levels of review for construction projects. Construction projects of greater complexity and higher costs undergo full review, requiring submission of a CON application that includes a series of forms and schedules and a detailed review for financial feasibility and public need. PHHPC must be afforded an opportunity to

make a recommendation on full review construction projects, while the ultimate determination of whether to approve such projects lies with the Commissioner.

Applications that undergo administrative or limited review may be approved by the Commissioner without the recommendation of PHHPC. Administrative review requires a CON application including forms and schedules which are less detailed than those needed for full review, and involves review for financial feasibility and public need. Limited review requires a narrative describing the construction activity to be undertaken, the cost of the construction and where applicable, architecture/engineering drawings or certification and does not include review for financial feasibility or public need.

Section 710.1(c)(1) specifies that CON applications are necessary for certain types of construction projects, generally including the addition, modification or decertification of licensed services, changes in the method of delivery of a licensed service, regardless of cost, or the acquisition or addition of equipment. Subsequent paragraphs delineate the criteria by which projects are assigned an appropriate level of review based on the type of action, the services and specific circumstances of a project as well as the project cost.

Section 710.1(c)(2) provides that "full review" is required for construction applications that involve the addition of beds, the addition or modification of a change in delivery for certain services, and proposals involving total project costs in excess of $15 million. Section 710.1(c)(3) provides that projects eligible for "administrative review" generally include those with a total project cost that does not exceed $15 million. However, an application shall be eligible for administrative review even though total project costs exceed $15 million, if: (a) total project costs do not exceed 10 percent of the total operating costs of the facility for the fiscal year ended two years prior to the submission of the application; and (b) total project costs do not

exceed $50 million for a general hospital or $25 million for all other facilities. Further, under section 710.1(c)(3)(i)(q), administrative review also applies to proposals related to health information technology (HIT) with a total cost above $15 million.

Section 710.1(c)(5) identifies construction projects subject to "limited review," which generally includes projects with costs that do not exceed $6 million. Pursuant to section 710.1(c)(5)(ii), limited review also applies to non-clinical projects involving heating, ventilating, air conditioning, plumbing, electrical, water supply and fire protection systems where such projects involve the modification or alteration of clinical space, services or equipment. Section 710.1(5)(iv)(g) further provides for limited review of any proposal to acquire, install or modify HIT that does not cost more than $15 million.

Section 710.1(c)(4) provides that certain construction projects do not require review but require written notice to the Department. Such projects include non-clinical infrastructure projects (other than projects affecting clinical space, which would require limited review as noted above).

Needs and Benefits:

Over the last several years, the Department has refined the CON process to ensure that it continues to advance its objectives, is responsive to a changing health care environment, focuses Department and PHHPC resources on issues and projects with the greatest impact, and is as streamlined and expeditious as possible within the parameters of the statutory authority.

This proposal represents the next phase of CON streamlining measures and will: (1) raise the monetary thresholds impacting the level of review for "general hospital" construction projects; (2) eliminate the requirement that notice be provided for non-clinical infrastructure

projects that do not exceed $6 million; (3) eliminate the requirement for Department approval of HIT projects, instead requiring notice which, for HIT projects impacting patient care, will include certification as to interoperability and compliance with other applicable requirements; (4) update language to require that construction applications be submitted electronically; and (5) correct several erroneous references within the regulation. The proposal does not modify the level of review required to add, reduce or decertify medical services in a community.

Section 710.1(c)(2)(i)(c) will be amended to subject "general hospital" construction projects to full review if they exceed $30 million. Section 710.1(c)(3)(i) will be amended to require administrative review if costs are not more than $30 million for "general hospitals" or, if in excess of $30 million, no more than 10 percent of operating costs and no more than $100 million. Section 710.1(c)(1)(vi) will be amended to raise the threshold for limited review of a general hospital construction project to $15 million.

These increases recognize the overall upward movement in construction costs for large-scale projects undertaken by "general hospitals". The relative size of operating budgets and accumulated financial resources of applicants other than "general hospitals" make the current dollar thresholds still appropriate for those facilities.

In addition, section 710.1(c)(4)(i)(e) will be amended to apply the notice requirement to non-clinical infrastructure projects costing over $6 million. A new section 710.1(c)(4)(ii) will reflect that neither review nor notice is required for non-clinical infrastructure projects that do not exceed $6 million. Both provisions will reflect, however, that non-clinical projects impacting clinical spaces, services or equipment will continue to be subject to limited review under section 710.1(c)(5)(ii)(d).

Section 710.1(c)(3)(i)(q), which subjects HIT projects to administrative review if they are over $15 million, and section 710.1(c)(5)(iv)(g), which subjects HIT projects to limited review if they are no more than $15 million, will be repealed. A new section 710.1(c)(4)(i)(g) will provide that Department review of HIT projects is not required, but a facility will be required to provide notice to the Department that it is undertaking such a project. For HIT projects involving systems that impact patient care, the notice will have to include certification as to the system's interoperability and conformance with state and federal guidelines governing the use and exchange of information.

Finally, this proposal will amend section 710.1(c)(6)(ii)(b), related to limited review cardiac catheterization proposals, to update language and clarify that applications must be submitted electronically, consistent with Department practice.

The measures included in this streamlining initiative will continue to reflect the overall objective of the statutory and regulatory framework, as set forth in 10 NYCRR section 710.1(a), to help ensure that medical facilities are planned to achieve efficiency and economy of operation and care of high quality. At the same time, it will help support regulated providers in meeting heightened demands to be increasingly agile given ongoing health system reform and evolving trends in medicine. Further, these changes are consistent with a broader effort being undertaken by the Department, in consultation with stakeholders, to fundamentally restructure health care statutes, regulations and policies to better align with changes in the health care system, affording opportunities to streamline requirements and promote flexibility that supports efficiency and innovation.

COSTS:

Costs to Private Regulated Parties:

The proposed amendments will not increase costs for private entities subject to the requirements of PHL Article 28 and in fact are expected to have a favorable fiscal impact. Some applicants either would no longer need to submit a CON application or would need to prepare a less complex application, meaning that they will pay less in application fees, which are required in higher amounts for applications requiring higher levels of review. These changes also should expedite the time for approval of projects and therefore minimize costs related to construction delays.

Costs to Local Government:

This proposal will not impact local governments unless they operate a general hospital, in which case they are likely to experience decreases in costs as noted above with respect to private entities.

Costs to the Department of Health:

This proposal is not anticipated to have a fiscal impact on the Department.

Costs to Other State Agencies:

The proposed regulatory changes will not result in additional costs to other State agencies.

Local Government Mandates:

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

Paperwork:

The proposed amendments will impose no new reporting requirements, forms or other paperwork. The amendments will reduce paperwork by shifting projects to lower levels of review or removing the requirement for the filing of a CON application.

Duplication:

This rule does not duplicate any other law, rule or regulation.

Alternatives:

The Department considered higher increases of the monetary thresholds but ultimately determined that the amounts included in the proposal reflect an appropriate balance between the recognition of increased construction costs for large-scale projects and the desire to maintain sufficient oversight for purposes of promoting high quality services aligned with community need.

Federal Standards:

The proposed amendments do not exceed any minimum standards of the Federal government. There are no Federal rules currently addressing the CON process.

Compliance Schedule:

These regulations will be effective upon publication of a Notice of Adoption in the New York State Register and would apply to all construction applications submitted thereafter. Consequently, regulated parties should be able to comply with the proposed regulation as of its effective date.

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STATEMENT IN LIEU OF
REGULATORY FLEXIBILITY ANALYSIS
FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

No regulatory flexibility analysis is required pursuant to section 202-(b)(3)(a) of the State Administrative Procedure Act. The proposed rule will not have a substantial adverse impact on small businesses or local governments.

STATEMENT IN LIEU OF
RURAL AREA FLEXIBILITY ANALYSIS

No rural area flexibility analysis is required pursuant to section 202-bb(4)(a) of the State Administrative Procedure Act. The proposed amendments will not impose an adverse impact on facilities in rural areas, and will not impose reporting, record keeping or other compliance requirements on facilities 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 this proposed regulation.

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 filing with the Secretary of State:

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;

A 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.

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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 on an emergency basis upon filing with the Secretary of State.

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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. 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.

EMERGENCY JUSTIFICATION

This proposal represents a response to the prevalence of substance use disorder 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.[6] Recently, for the first time, admissions to programs operated or certified by the Office of Alcoholism and Substance Abuse Services (OASAS) for substance use disorders surpassed the number of admissions for alcohol use. 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.

Individuals with substance use disorders often present to emergency departments after an overdose and are discharged after being stabilized but, as recognized by the Heroin and Opioid Task Force, "an opportunity is missed to connect them to treatment services."[7] Moreover, opportunities to identify such individuals and their needs is not limited to the emergency department. Accordingly, PHL § 2803-u was enacted to require general hospitals to institute policies and procedures to identify, assess and refer individuals with substance use disorders when admitted to, treated in and discharged from hospital units including emergency departments. Further, such policies and procedures must encompass the provision of education materials about substance use disorder services during discharge planning and connected with needed substance use disorder services. This proposal will implement these statutory provisions by providing parameters for hospitals to carry out the requirements of the statute.

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[6] *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.

[7] Id. at p. 14.

Similarly, this proposal seeks to address the current crisis by requiring the Department of Health, in consultation with OASAS, to create a pamphlet including a "voluntary non-opioid directive" form, which will allow individuals to document their desire for health care practitioners to refrain from offering or providing them with opioids. This proposal recognizes such "voluntary non-opioid directive" as a form of advance directive, permitting individuals to express preferences about their health care consistent with the Health Care Proxy Law and the Family Health Care Decisions Act.

This proposal builds upon existing efforts by state agencies, hospitals and other health care providers to implement initiatives that connect individuals with substance use disorder services. Given the scope of the current crisis, and the urgency of connecting individuals to needed services as soon as possible, it is necessary to promulgate the regulations on an emergency basis.

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.

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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.

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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. 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.