Spurring Health Care Innovation through Regulatory Modernization

PUTTING PATIENTS FIRST

NEW YORK STATE | Department of Health | Regulatory Modernization Initiative

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SPURRING HEALTH CARE INNOVATION THROUGH REGULATORY MODERNIZATION

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Introduction

Under the leadership of Governor Andrew M. Cuomo, New York State has led the nation in transforming its health care delivery system. Together, Governor Cuomo's Medicaid Redesign Team (MRT), the Delivery System Reform Incentive Payment (DSRIP) Program and the New York State Health Innovation Plan (SHIP) are breaking down service silos and fostering collaborations among health care providers to increase quality, reduce costs and improve people's health.

Yet, as these initiatives have been implemented across the State, it has become clear that New York's health care regulations are in need of fundamental reform. The rapid pace of health care innovation and reform has outpaced the ability of New York State's regulatory structure to adapt, resulting in a regulatory landscape that can be complex and outdated. Payers, providers, and patients alike have expressed concern that this landscape can impede their ability to deliver and receive the high-quality, value-based care that New Yorkers deserve.

To address this, in 2017, Governor Cuomo directed the New York State Department of Health (DOH) to launch a new process aimed at reforming the policies and regulations that govern the licensure and oversight of health care services and facilities, with a patient-centered focus. Through the Regulatory Modernization Initiative (RMI), DOH convened six workgroups to solicit recommendations from health care providers, consumers, and payers in order to streamline and improve policies, regulations, and statute. The workgroups were: Integrated Primary Care and Behavioral Health; Telehealth; Post-Acute Care Management Models; Cardiac Services; Off-Campus Emergency Departments; and Long Term Care Need Methodologies and Innovative Models.[1]

Each workgroup was comprised of external stakeholders who are subject matter experts in their fields, spanning diverse backgrounds, as well as staff from DOH, Office of Mental Health (OMH), Office of Alcoholism and Substance Abuse Services (OASAS) and Office of People With Developmental Disabilities (OPWDD). Members of the Public Health and Health Planning Council (PHHPC) also joined many of the RMI workgroups and, of course, members of the public participated by sharing comments and feedback on the issues that impact their lives. Together, these workgroups produced a series of recommended changes to existing statute, regulation, and policy for consideration by DOH, as well as other state agencies where appropriate.

[1] The Long Term Care Needs Methodologies workgroup is still in progress. The final recommendations of the Long Term Care Need Methodologies workgroup and the Department's next steps will be released in an amended version of this report; expected later in the first quarter of calendar year 2018.

This report outlines all workgroup recommendations, highlights the steps that DOH has taken to implement recommendations to date, and previews next steps for DOH moving into 2018.

Much work remains as we continue to make our health care delivery system work better for all New Yorkers. DOH will continue to take the necessary steps to facilitate an environment where providers, payers, and patients are best positioned to ensure access, improve safety and quality, and lower costs—and to build a system for tomorrow that puts patients first.

Integrated Primary Care and Behavioral Health:
Providing patients with one access point for primary care and behavioral health services

I. Overview:

A growing body of evidence confirms that the integration of primary and behavioral health services can improve the quality of care and lower costs. And yet, while many patients face both physical and behavioral health care needs, care is often provided in silos—impacting patients, providers, and payers alike.

Currently, in order to provide physical or behavioral health services, there are three separate sets of licenses, regulations, billing methodologies, and oversight processes for each service: primary care (DOH), mental health (OMH), and substance use disorder services (OASAS). In order to provide these services in a single clinic setting, providers must navigate a burdensome and inflexible maze of regulations. At-risk patients also face the need to navigate this complex system, which may result in them not receiving the care that they need.

While New York State has made important progress to integrate the delivery of these services through initiatives such as DSRIP, much work remains. This workgroup considered the steps that New York State might take to continue the transition towards comprehensive integration. In particular, the workgroup examined the possibility that the State create a new streamlined licensure model which would ease administrative burdens for providers aiming to coordinate care and provide patients at a singular access point in a way that increases access, improves quality, and lowers cost.

II. Actions to Date:

Recognizing the need to move towards integration, and the impact integration can have on patient populations, New York State has taken a number of steps to better facilitate integrated, coordinated care.

In January 2015, New York State announced a new model for integration called the Integrated Outpatient Services Regulations (IOS)[2]. Under this model, a provider licensed or certified by more than one agency may add services at one of its sites (the "host" site) without the need for additional licensure or certification at the desired clinic setting. The IOS regulations also provide for a common set of operating and physical plant standards in order to ease administrative burden and minimize regulatory complexity. To date, OMH, OASAS and DOH have approved 77 IOS sites.

In addition, under current law and regulations, some providers—including Federally Qualified Health Centers (FQHCs), physician practices, Article 31 clinics, and Article 32 clinics—have

[2]Outpatient Services Regulations: 10 NYCRR Part 404, 14 NYCRR Parts 598 and 825

implemented a number of innovative approaches to deliver integrated primary care and behavioral health care.

For example, under DSRIP, a program referred to as "Project 3.a.i." facilitates integration by permitting certain providers to integrate services under a single license or certification provided certain qualifications are met. This has enabled providers to develop and implement new approaches. However, only a limited level of primary care and behavioral health services can be provided, and the model expires in 2020 with the conclusion of DSRIP.[3]

III. Obstacles:

The workgroup identified the primary barriers to integration as statutory and regulatory operating flexibility and reimbursement. Currently, entities that want to integrate services must deal with multiple rules regarding which patients can be served, such as different visit volume thresholds for different services. They must also satisfy multiple licensing requirements, apply different billing rules and codes, and abide by varying surveillance processes and rules. While New York State allows for some sharing of space and coordinated survey processes, these separate license categories, billing methodologies, and state oversight mechanisms present an unnecessary barrier to coordinated care that best meets patient needs. Although DSRIP has been a highly effective tool for integration, there is a need to consider a more permanent structure moving forward.

IV. Workgroup Recommendations:

1. <u>Create a simple and flexible model for integrated licensure.</u>

   - Create a new licensure category that would allow an existing clinic to add services without needing to obtain a second license. This model would enable the clinic to add primary care, mental health, or substance use services, so that providers can treat the whole patient, not just one aspect of the patient's needs.

2. <u>Develop incentives for providers to offer integrated services by making it easier to receive reimbursements.</u>

   - Allow DSRIP 3ai and IOS providers to be reimbursed for the delivery of behavioral health and physical health services or two behavioral health services on the same day; ensure that behavioral health providers can bill for physical health services and vice versa.

   - Ensure that Managed Care Organizations (MCO) reimburse providers who provide integrated care.

[3] DSRIP 3.a.i application instructions: https://www.health.ny.gov/health_care/medicaid/redesign/dsrip/regulatory_waivers/draft_appl_instructions.htm

- Add flexibility to the requirement for the number of hours (16 hours per week or 8 with a waiver) that the primary care provider is required to work at a behavioral health site.

- Eliminate the 50% physical health discount for payment for an IOS mental health or OASAS host.

- Simplify the billing for Article 31 and Article 32 providers that need to bill for physical health services.

- Allow for non-FQHC Article 28 providers to be reimbursed for services provided by licensed mental health counselors.

- Allow FQHCs that use the PPS reimbursement rate to bill more than one threshold visit per day, while preventing double dipping.

3. Assessment of the need for a new license type (e.g. "Article 99" license).

   - After two years of assessing the success or shortcomings of the new licensure category, DOH, OMH and OASAS should perform an evaluation to determine if barriers to integration still exist. Should barriers still exist, the agencies should explore additional changes, including the creation of a new licensure type that would allow an extensive array of primary care, mental health and substance use services to be provided by clinics with oversight from a single State agency.

V. Next Steps:

1. DOH, OMH and OASAS will propose regulations to allow for the new licensure category, with standard requirements across all three agencies, and implement a streamlined licensure application and approval process.

2. DOH will amend Public Health Law to remove the limitation on primary care visits that can be provided. Mental Hygiene Law will also be amended to facilitate delivery of mental health and substance use disorder services by any provider authorized pursuant to an integrated licensure authority.

   - **Article VII language introduced in the 2018-19 Executive Budget would implement this recommendation.** [4]

[4] Executive Budget Health and Mental Hygiene Article VII: Subpart A of Part S of S.7507/A.9507

3. DOH will provide guidance to allow DSRIP 3ai and IOS providers to be reimbursed for the delivery of behavioral health and physical health services or two behavioral health services on the same day, and ensure that providers of behavioral and physical health can bill for both services.

   - **The September 2017 Medicaid Update Volume 33 Number 9 provided instruction for providers to receive such payment.[5]**

4. DOH will address reimbursement issues between managed care organizations (MCOs) and providers of integrated care.

   - **DOH, OMH and OASAS have established an Integrated Billing Workgroup consisting of payers and providers to address this issue. The group held its first meeting on December 8, 2017 and will meet twice a month moving forward.**

VI. Workgroup Meeting Dates:

The workgroup met on August 17, 2017 and October 13, 2017 at the Empire State Plaza in Albany, New York.

VII. Workgroup Members:

Co-Chairpersons

- **John Rugge, MD** Hudson Headwaters Network
- **Ann Monroe** DSRIP Project Approval and Oversight Panel
- **Jennifer Treacy** NYS Department of Health

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- **Udo Ammon** NYS Department of Health
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[5]Medicaid Update: https://www.health.ny.gov/health_care/medicaid/program/update/2017/2017-09.htm

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Post-Acute Care Management Models:
Putting patients at the center of a coordinated, cohesive health care system with smooth care transitions

I. Overview:

Health care stakeholders have long agreed on the importance of supporting the delivery of services across an integrated system of care. For post-acute care, in particular, it is widely acknowledged that achieving care coordination is critical to reducing readmissions and improving a host of patient outcomes, while slowing the growth in costs.

Yet, many health care and home care providers face challenges in post-acute care management, with stakeholders expressing concern that the State's regulatory landscape is impeding the delivery of new, innovative models that allow for more seamless care transitions. In addition, patients and their families have highlighted the need to improve access to high-quality post-acute care in order to keep themselves and their family members healthy and well.

To address these concerns, this workgroup examined how existing State laws and regulations could be adapted to better enable providers to deliver services known to reduce readmissions and improve patient outcomes. Focusing in particular on Public Health Law (PHL) Articles 28 and 36, the workgroup outlined a series of proposals aimed at supporting access to care and enabling innovative care delivery models, while safeguarding patients and their families.

II. Actions to Date:

New York State is committed to facilitating coordinated care across a range of settings, and has taken several steps to do so.

Under DSRIP, New York State has issued conditional waivers of Section 401.2(b) of Title 10 of the NYCRR allowing Provider Performing Systems to apply to have practitioners of Article 28 facilities provide services outside of the designated site of operation as listed on the facility's operating certificate.[6] DOH is in the process of developing clarification regarding what services can be provided through these conditional waivers. In addition, in 2015, New York's Hospital-Homecare-Physician Collaboration law was enacted to facilitate innovation in meeting a patient's health care needs in the community setting. The new law provides the framework for collaboratives including hospitals, nursing homes, home care agencies and physician practice models to work together to improve patient care access and outcomes.

At the federal level, alternative models for health care delivery piloted by the Center for Medicare & Medicaid Innovation (CMMI) specifically include care delivered by physicians, nurses and other health professionals in a home-based setting.

[6]Section 401.2(b): https://regs.health.ny.gov/content/section-4012-limitations-operating-certificates.

III. Obstacles:

Initial discussion of the workgroup suggested that, currently, no single model of post-acute care emerges as the optimum standard of care. Stakeholders highlighted difficulties securing home care services through established agencies in the immediate hours (sometimes days) after a patient's discharge from a hospital. The workgroup pointed to a number of contributing factors, most notably: reimbursement levels; a lack of coordination between the hospitals and home care agencies; low capacity of existing providers; and billing rules prohibiting the hospital and post-acute care provider to charge for services provided on the same day.

The workgroup also identified broader structural challenges that contribute to the post-acute care management issue. These challenges included workforce deficits; lack of support for software and infrastructure related to technology; and an insufficient use of telehealth. Many of these issues were beyond the immediate scope of the workgroup, although important to consider as recommendations are proposed. The workgroup recommended that proposed solutions align with the resources that are available in order to support the current needs of post-acute patients.

IV. Workgroup Recommendations:

1. Provide legal authority for community paramedicine programs.

   - Current Emergency Medical Technician (EMT) scope of practice does not allow EMTs to perform duties in non-emergency situations and prohibits providers from directly billing for services provided.

2. Implement demonstration projects under the Hospital-Home Care-Physician Collaboration Program (PHL Section 2805-x).

   - PHL Section 2805-x includes language that supports innovation in hospital, home care agencies, and physician offices in meeting the community's health needs. The statute "provides a framework to support voluntary initiatives in collaboration to improve patient care access and management, patient health outcomes, cost-effectiveness in the use of health care services and community population health." [7]

3. Offer general education on Advanced Care Planning.

   - Education should be provided to providers and the public to obtain a better understanding of advanced care planning, hospice, and palliative care.

[7] NY Public Health Law § 2805-X (2015): http://public.leginfo.state.ny.us/lawssrch.cgi?NVLWO:

The following recommendations did not have a consensus of Committee members; however, the Department will continue to review and evaluate their respective merit.

4. Revise the Consumer Directed Personal Assistance Program regulations.

   - Current regulations do not allow payment to the Patient Assistant while the patient is hospitalized. Revision to the regulations would allow the Patient Assistant to receive one to five hours of payment during the patient's hospitalization to receive training and information during the discharge process.

5. Provide clarification on conditionally approved DSRIP waivers.

   - Select PPS systems opted to apply for a waiver of 10 NYCRR 401.2(b), to allow the provision of off-site services in the home. These waivers were approved conditionally and contingent upon the submission of additional documents. Not all PPSs that applied for this waiver complied with this contingency.

6. Require insurers to expedite review and authorization decisions.

   - Delays in insurer review and determination of authorization for post-acute services delays discharge from the acute care setting, as most post-acute care providers will not accept a patient without prior authorization.

7. Establish a lead care coordinator for discharge events.

   - Discharge from an acute setting to a post-acute setting includes multiple parties, potentially disrupting communication and limiting the ability to have a smooth transition.

8. Expand scope of practice for nurses in assisted living residences and adult homes.

   - Nurses employed by assisted living residences and adult homes are limited by regulations and unable to work within their full scope of practice in these settings. Nurses are unable to assess and must transfer residents to an acute care setting for evaluation, potentially resulting in hospitalization.

9. Modernize commercial coverage for home care.

   - The current state insurance law mandate was enacted several decades ago. A detailed review of the provisions and an amendment to modernize the language would increase 3rd party commercial coverage of home care services.

10. Provide more discharge planner education to all involved staff.

    - Inpatient case managers must be aware of the full range of services available to patients as they prepare to transition home.

11. Eliminate the Patient Review Instrument.

    - Currently, hospitals conduct the Patient Review Instrument (PRI) assessment prior to discharge from the hospital to a nursing home. The PRI assessments tend to have minimal value due to hospital discharge staff's lack of familiarity with the patient and absence of a hospital purpose for the PRI. Within a reasonable period of time after admission to the nursing home, a complete assessment is conducted by the nursing home using the Resident Assessment Instrument. Under managed care and emerging VBP arrangements, there is significant pressure to reduce nursing home utilization. Accordingly, the PRI is no longer necessary to prevent inappropriate utilization. The department will work with stakeholders on the implementation of a new process and documentation for admission decisions.

V. Next Steps:

1. DOH will propose statutory changes necessary to implement community paramedicine by authorizing EMT's to provide services for which they are trained and certified in non-emergent situations and under medical supervision. The proposal will allow services to be deployed in ways that reduce the need for more expensive levels of care and allow for billing of services if engaged in value-based payment arrangements.

    - **Article VII language introduced with the 2018-19 Executive Budget would implement this recommendation.[8]**

2. DOH will issue guidance and provide education related to PHL Section 2805 x in order further post-acute collaboration.

    - **DOH issued guidance in the form of a Dear Administrator Letter (DAL) on December 19, 2017.[9]**

3. DOH will provide resources for telehealth and other health information technology investments in support of post-acute care services in the community.

[8] Executive Budget Health and Mental Hygiene Article VII: Subpart A of Part S of S.7507/A.9507
[9] Dear Administrator Letter:
https://www.health.ny.gov/regulations/regulatory_modernization_initiative/docs/pacm_phl2805_dal.pdf

- **The 2018-19 Executive Budget provides new funding for the Health Care Facility Transformation Program ("Statewide III"), which includes support for information technology resources to strengthen the acute, post-acute and long-term care continuum.[10]**

4. DOH will develop a comprehensive, multi-disciplinary advanced care planning proposal that engages both providers and the public. Education will be provided to providers and the public to obtain a better understanding of advanced care planning, hospice, and palliative care.

5. DOH will issue a Request for Information in relation to the recommendation to replace the PRI. The PRI is obsolete, and a new process and documentation for nursing home admissions is needed.

VI. Workgroup Meeting Dates:

The workgroup met on August 9, 2017 at the Empire State Plaza in Albany, New York. The second meeting of the workgroup took place on September 18, 2017 at the New York Academy of Medicine in New York City.

VII. Workgroup Members:

Co-Chairpersons

- **Mark Kissinger** NYS Department of Health
- **Sara Butterfield** Island Peer Review Organization

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[10] Executive Budget Health and Mental Hygiene Article VII: Part Q of S.7507/A.9507

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Cardiac Services:
Increasing access to high quality cardiac procedures and cardiac surgery

I. Overview:

The Certificate of Need (CON) regulations for Cardiac surgery and percutaneous coronary intervention (PCI) are based on the premise that a minimum volume of procedures or surgeries at a specific hospital location is necessary in order to ensure a sufficient level of quality. However, since these regulations were first promulgated, significant advances in technology and medical practice have made PCI and cardiac surgery procedures safer. In addition, standalone community hospitals are increasingly becoming part of integrated regional health care networks that are anchored by large academic medical centers. This transformation is increasing the potential for expanded access to quality cardiac care in these communities.

This workgroup explored the statutory, regulatory and policy provisions governing the CON process for cardiac surgery and PCI services in New York State, with the goal of ensuring that patients can access high-quality cardiac programs as conveniently as possible. The workgroup proposed a series of measures that would update the cardiac CON process to recognize new systems of care, while safeguarding the safety and quality of services.

II. Actions to Date:

Over the past several years, DOH and the Public Health and Health Planning Council have taken numerous steps to streamline the CON process. Despite this progress, changes to the cardiac services need methodologies have not advanced. In the meantime, DOH continued to receive applications to establish new PCI and cardiac surgery programs, many of which would provide greater access and choices to patients seeking high quality cardiac services, but could not be approved under existing regulations. Some of these applications have remained in a pending state for up to two years. As a result of this situation, hospitals (both those with established programs and those seeking to establish new programs) have asked DOH to update and clarify the applicable regulations.

III. Obstacles:

Existing CON regulations for cardiac services are primarily based on the premise that a minimum annual volume of procedures at a given hospital is needed to ensure an acceptable level of quality. Under existing regulations, to receive approval, a hospital proposing a new cardiac surgery or PCI program must demonstrate that it can achieve the annual minimum facility volume threshold, and that any existing cardiac program in the planning area will maintain this minimum facility volume threshold after the new provider is operating. These regulations were last updated in 1999 when PCI was still a relatively new procedure and not performed using the minimally invasive technology that is available today.

These regulations also date back to when PCI was first permitted to be performed at hospitals that did not have cardiac surgery on site. Recent outcome (mortality rate) data indicates that PCI programs have comparable outcomes despite hospital facility volume levels (See Appendix A).

The existing CON regulations have the effect of limiting new program entrants into geographic markets, and are also not aligned with the increasing prevalence of integrated regional health care systems that are operated and governed by large academic medical centers. Such systems improve the coordination and delivery of health care services and help improve quality and ensure the financial sustainability of community hospitals within the network. In such systems, the co-established parent hospital governs the member hospitals through its reserve powers. Several of these systems have achieved broad clinical integration, including joint clinical department heads, quality assurance and training programs, information systems with data exchange and the sharing of clinical and support staff such as specialty teams.

Based on research presented by the University at Albany School of Public Health, the workgroup recognized that the correlation between volume and outcomes for PCI services has decreased in importance but that some minimal threshold is still needed. The workgroup also acknowledged the importance of maintaining and improving access to emergency PCI for acute coronary syndrome 24/7/365.

IV. Workgroup Recommendations

1. <u>PCI Programs (no cardiac surgery) – Public Need Determination:</u>

   - Amend regulations to introduce public need criteria for two models of care:

     - PCI applicant facilities that are co-established within a system, where the "active parent" hospital has an approved cardiac surgery/PCI license.[11]

     - PCI applicant facilities that are not co-established, and are proposing a clinical cardiac affiliation agreement between an existing licensed cardiac surgery/PCI provider ("sponsoring hospital") and a new PCI provider.

[11] Co-established means that each hospital has the full legal authority and responsibility of being established and enjoys the full governance powers as outlined in 10 NYCRR 405.3(f)(3).

- For co-established hospitals within a system, the criteria shall include: evidence that at least one hospital within the co-established system is licensed as a cardiac surgery program with a PCI capable cardiac catheterization lab; the applicant facility demonstrates that it can achieve 36 emergency PCI procedures per year within first year of operation; that one facility within the system meets a minimum volume threshold of 600 PCI procedures at a steady state; and that hospitals offering PCI services within the system have a staff sharing agreement, including rotations and training of staff with the sponsoring facility as well as participation in all quality and patient safety activities.

- For entities that are not co-established and the applicant hospital has a cardiac clinical affiliation agreement with a hospital that has a licensed cardiac surgery program and PCI capable lab ("sponsoring hospital"), criteria shall include: the applicant facility demonstrates that it can achieve 36 emergency PCI procedures per year within first year of operation; the sponsoring facility meets a minimum volume threshold of 600 PCI procedures at a steady state; and the sponsoring hospital and the applicant facility must have a staff sharing agreement, including rotations and training of staff with the sponsoring facility as well as participation in all quality and patient safety activities.

- The workgroup also recommended that under both co-established and sponsoring hospital models, the following volume criteria currently required by regulation, should be eliminated:

    - 200 total PCI procedures within two years of operation at new applicant facility;

    - 300 total PCI procedures per year at a steady state at new applicant facility; and

    - All existing facilities in the planning area must continue to meet the minimum facility volume requirement of 300 total PCI procedures per year after the addition of the proposed new program

- The workgroup recommended the continuation of the current regulatory definition of the planning or use area as one-hour average surface travel time from applicant facility, adjusted for traffic patterns and weather conditions.

2. PCI (no Cardiac Surgery) Program Workload Requirements:

   - Current regulations require a minimum facility volume of 150 PCI procedures per year, including at least 36 emergency cases. The regulations further require that PCI Centers that do not meet these minimal volume standards for two consecutive calendar years shall surrender their license or have approval revoked. The workgroup recommended:

     - Keeping the minimum workload volume standard that PCI Centers must maintain 150 PCI procedures per year including at least 36 emergency cases, but replace the requirement that if not met, the facility shall surrender its operating license or have it revoked with a requirement that the facility will be closely monitored for quality outcomes by the Department.

     - Eliminating current regulations that require PCI Centers with annual volume between 150 and 300 cases a year to procure the services of an independent physician consultant

     - Keeping existing program regulations that require at least three interventional cardiologists per program with at least one of whom dedicates the majority of his/her time at the applicant facility, and that each interventional cardiologist shall maintain sufficient facility volume to perform a minimum of 75 PCI cases per year of which 11 are emergency PCI, and not all 75 or 11 PCI cases must be performed at one site.

3. Adult Cardiac Surgery - Public Need Determination:

   - Current regulation requires minimum threshold volume requirement for new applicant facility of 500 cases per year at a steady state. The workgroup recommended:

     - Eliminating the 500 cases per year steady state requirement for the new licensed facility.

   - Current regulations provide that to approve a new Adult Cardiac Surgery Center, all existing Centers in the planning area must continue to meet the minimum facility volume requirement of 500 cases per year after the addition of the proposed new program. The workgroup recommended:

     - Eliminating the 500 cases per year steady state requirement for the existing licensed facilities in the planning area.

V. Next Steps:

DOH will propose the regulatory changes pertaining to CON regulations for cardiac surgery and PCI. The most significant change will be that the regulations will reflect two new models of care; one in which the applicant is co-established within a hospital system and the second in which the applicant is proposing a clinical cardiac affiliation agreement between an existing licensed cardiac surgery/PCI (sponsoring hospital) and a new PCI provider. The table below details the proposed regulatory changes:

Current Regulations	**Proposed amendments for co-establishment model**	**Proposed amendments for sponsor model**
PCI Public Need Regulations (709.14)[12]		
Same standards for all applicant facilities requesting a new service, primarily using estimated case volume but also impact on other facilities, travel time, and special community preferences that affect access to life-saving care.	Separate standards for co-established entities	Separate standards for an applicant with a sponsor relationship. A PCI program applicant must have a clinical cardiac affiliation agreement acceptable to the Department with an existing licensed cardiac surgery/PCI provider ("sponsoring hospital").
CON application submitted by the facility where PCI services will be provided.	CON application must be submitted jointly by the new applicant facility and co-established parent/system. Accountability for program rests with system.	CON application submitted by the new applicant facility where PCI services will be provided. Accountability for program rests with PCI applicant facility.
Staff sharing agreements. Not currently addressed in regulations.	Facilities within the system that offer PCI services must have a staff sharing agreement including rotations and training of staff with the co-established parent/system as well as integration into system's quality and patient safety activities.	The affiliation agreement with sponsoring hospital must include a staff sharing agreement, including rotations and training of staff as well as participation in all quality and patient safety activities.

[12]PCI Public Need Regulations (709.14): https://regs.health.ny.gov/content/section-70914-cardiac-services

Current Regulations	Proposed amendments for co-establishment model	Proposed amendments for sponsor model
PCI Public Need Regulations (709.14)		
	The co-established parent/system will be responsible for maintaining the competency of the cardiac interventionalist physicians, nursing and technical staff performing services at the new applicant facility by providing training and rotational opportunities at higher volume facilities within the system.	The affiliation agreement with the sponsoring hospital must address how the competency of the cardiac interventionalist physicians, nursing and technical staff providing services at the new applicant facility will be maintained by providing training and rotational opportunities.
	The co-established parent/system will be responsible for ensuring that the new applicant facility can provide "24/7/365" coverage.	The affiliation agreement with the sponsoring hospital must address how the new applicant facility will provide "24/7/365" coverage.
	The co-established parent/system will be responsible for providing quality assurance, peer review and patient safety programs.	The affiliation agreement with the sponsoring hospital will require the sponsor to provide quality assurance, peer review and patient safety programs the new applicant facility will participate in.
Requests considered within geographic framework, a Planning or use area: one-hour average surface travel time from applicant facility, adjusted for traffic patterns and weather conditions. Process for exemptions then follows.	Keep one-hour planning area	Keep one-hour planning area

Current Regulations	Proposed amendments for co-establishment model	Proposed amendments for sponsor model
PCI Public Need Regulations (709.14)		
Standard includes minimum threshold volume requirement for new applicant facility: • 36 Emergency PCI procedures in first year • 200 total PCI procedures within two years of operation • 300 total PCI procedures per year at a steady state	Standard includes minimum threshold volume requirement for new applicant facility: • 36 Emergency PCI procedures in first year- remains the same • Eliminate requirement for 200 total PCI procedures within two years of operation • Eliminate requirement for 300 total PCI procedures per year at a steady state • Add new requirement that a hospital within the co-established system must be a licensed cardiac surgery program and catheterization lab with TBD total PCI procedures per year at a steady state. [TBD threshold will be determined based on further evaluation of outcome data from existing PCI programs] If the system cardiac surgery program is not in the planning area, then PCI applicant must have an emergency transfer agreement with a hospital in the planning area that has cardiac surgery program on site.	Standard includes minimum threshold volume requirement for new applicant facility: • 36 Emergency PCI procedures in first year- remains the same • Eliminate the requirement for 200 total PCI procedures within two years of operation • Eliminate requirement for 300 total PCI procedures per year at a steady state • Add new requirement for 600 total PCI procedures at sponsoring facility which has cardiac surgery program on site, and must be in the planning area.

Current Regulations	Proposed amendments for co-establishment model	Proposed amendments for sponsor model
PCI Public Need Regulations (709.14)		
To approve a new PCI Center, all existing facilities in the planning area must continue to meet the minimum facility volume requirement of 300 total PCI procedures per year after the addition of the proposed new program.	Eliminate this requirement	Eliminate this requirement
PCI Program Regulations (405.29)[13]		
Each interventional cardiologist operating at the new applicant facility must perform a minimum of 75 total PCI procedures per year of which 11 must be emergency cases; not all must be performed at one site.	Keep this requirement	Keep this requirement
Each PCI center must maintain a minimum volume of 150 cases per year, at least 36 of which must be emergency cases.	Keep this requirement	Keep this requirement
PCI centers with annual volume below 150 cases per year for two consecutive years or a volume below 36 emergency cases shall surrender approval to perform PCI services or have approval revoked by the Department.	Amend to eliminate surrender/revocation requirement and replace with heightened monitoring by Department with option for revocation based on quality concerns.	Amend to eliminate surrender/revocation requirement and replace with heightened monitoring by Department with option for revocation based on quality concerns.
PCI centers with annual volume between 300 and 400 cases shall undergo a review of cases by the Department to evaluate the appropriateness and quality of care.	Eliminate this requirement	Eliminate this requirement

[13] PCI Program Regulations (405.29): https://regs.health.ny.gov/content/section-40529-cardiac-services

Current Regulations	Proposed amendments for co-establishment model	Proposed amendments for sponsor model
PCI Public Need Regulations (709.14)		
PCI Centers with an annual volume of between 150 and 300 cases a year must procure the services of an independent consultant to conduct annual review of appropriateness and quality of care.	Eliminate this requirement	Keep this requirement
Priority consideration shall be given to applicants that agree to serve medically indigent patients regardless of payment.	Keep this requirement	Keep this requirement

DOH will propose the following regulatory changes pertaining to public need for Adult Cardiac Surgery Programs:

Current Regulations	Proposed amendments for co-establishment model	Proposed amendments for sponsor model
Adult Cardiac Surgery Public Need Regulations (709.14)		
Minimum threshold volume requirement for new applicant facility: • 500 cases per year at a steady state	Lower threshold to TBD level based on further evaluation of outcome data from existing cardiac surgery programs.	Lower threshold to TBD level based on further evaluation of outcome data from existing cardiac surgery programs.
To approve a new Adult Cardiac Surgery Center, all existing Centers in the planning area must continue to meet the minimum facility volume requirement of 500 cases per year after the addition of the proposed new program.	Eliminate the requirement	Eliminate the requirement
Priority consideration will be given to applicants that serve the medically indigent and patients regardless of the source of payment.	Keep this requirement	Keep this requirement
Adult Cardiac Surgery Program Regulations (405.29)		
Adult cardiac surgery centers shall maintain an annual minimum of 100 procedures.	Keep this requirement	Keep this requirement

II. Workgroup Meeting Dates:

The workgroup met on October 16, 2017 at the Empire State Plaza in Albany, New York and November 8, 2017 at 90 Church Street, New York City, New York.

VI. Workgroup Members

Co-Chairpersons

- **John Morley, MD** Adirondack Health Institute
- **Marcus Friedrich, MD** NYS Department of Health

Members

- **George Alfieris, MD** University of Rochester Medical Center
- **Hashmat Asraf, MD** Buffalo General Medical Center
- **Chuck Bell** Consumers Union
- **John Bennett, MD** Capital District Physician's Health Plan
- **Albert Blankley** Common Ground Health
- **Larry Chinitz, MD** New York University
- **Sean Doolan** Hinman Straub, for Excellus BCBS
- **John Fox, MD** Mt. Sinai Beth Israel
- **Robert Frankel, MD** Medical Society of the State of NY
- **Mario Garcia, MD** Montefiore Medical Center
- **Leonard Girardi, MD** Weill Cornell Medicine
- **Jeffrey Gold, MD** University of Nebraska Medical Center
- **Bea Grause** Healthcare Association of NYS
- **Vivian Ho** Rice University
- **Alice Jacobs, MD** Boston University School of Medicine
- **Barry Kaplan, MD** Northwell
- **Suzanne Sullivan** NYS Board of Nursing
- **Fred Venditti, MD** Albany Medical Center
- **Gary Walford, MD** Johns Hopkins University
- **Zeynep Sumer-King** Greater NY Hospital Association
- **Stephen Ferrara** The Nurse Practitioner Association of NYS
- **David Jackson** NYS Society of Physician Assistants
- **Jeanne Alicandro** NYS Department of Health
- **Joan Cleary-Miron** NYS Department of Health
- **Kim Cozzens** NYS Department of Health
- **Mark Furnish** NYS Department of Health
- **Brian Groski** NYS Department of Health
- **Ed Hannan** NYS Department of Health
- **Eugene Heslin, MD** NYS Department of Health
- **Lisa McMurdo** NYS Department of Health

- **Mark** **Noe** NYS Department of Health
- **Tracy** **Raleigh** NYS Department of Health
- **Jennifer** **Treacy** NYS Department of Health
- **Linda** **Tripoli** NYS Department of Health
- **Gregory** **Young, MD** NYS Department of Health

Telehealth:
Allowing patients to access high quality care more conveniently using remote technology

I. Overview:

While New York State has made historic gains in increasing access to health care, more work remains to reach more New Yorkers, including those in rural areas, and to better enable convenient, consumer-driven care. The ability of telehealth to remotely connect patients and healthcare providers can be an important tool in ensuring access to health care, improving care and patient outcomes, enhancing patient satisfaction and reducing health care costs through improved population health.

Although telehealth has been used widely for many years throughout the United States and abroad, health care providers and systems in New York State have identified a number of challenges to the adoption and delivery of telehealth services, including financial, statutory and regulatory barriers. As a result, providers vary widely in the extent to which they have adopted these models, and the potential for telehealth to impact health care delivery in the state has not been fully realized.

This workgroup considered statutory, regulatory and policy changes to enable the adoption of emerging telehealth models and ensure that appropriate telehealth reimbursement is available. The workgroup also explored ways to streamline distinct regulations, rules and policies across State agencies to create an aligned set of principles governing the use of telehealth.

II. Actions to Date:

Though there is much work still to do, New York State has taken some important steps to leverage the use of telehealth to capitalize on innovation and further expand access to care. For example, in 2015, Governor Cuomo signed into law New York's Telehealth Parity Law, which required that commercial insurers and the Medicaid program provide reimbursement for services delivered via telehealth if those same services would have been covered in person. The Department of Health, which has provided reimbursement for telemedicine under the Medicaid Fee-for-Service program since 2006, has also taken steps to expand its coverage policy to additional settings and provider types in order to promote access and adoption.

III. Obstacles:

The workgroup identified several barriers to the adoption of telehealth as a means of delivering health care. Although New York's Telehealth Parity Law requires the Medicaid program and commercial insurers to provide reimbursement for services delivered via telehealth, stakeholders raised concerns about the statutory limitations placed on Medicaid reimbursement.

More specifically, the limitations on originating site requirements, eligible practitioner types, and permissible communication modalities have excluded from reimbursement some successful telehealth programs that have increased access to care and improved patient outcomes.

Providers have had difficulty understanding how to properly bill and successfully obtain Medicaid reimbursement for services delivered via telehealth, even when the services are delivered in a manner that falls within the statutory definitions outlined in the Telehealth Parity Law. Stakeholders cite an administrative burden with billing, as well as a general lack of clarity around which encounters can be reimbursed by Medicaid. Also, some Medicaid as well as commercial patients have reported being charged two co-payments (one from the "hub" site and one from the "spoke" site) for a single telehealth visit.

Under the current statutory language, as interpreted by DOH and DFS, commercial insurers have had greater flexibility in how, when and what types of telehealth interventions to cover. Stakeholders noted that the inconsistency between commercial insurer coverage policies adds to the complexity in provider understanding of which telehealth services are covered. Also, the rates of payment for services delivered via telehealth are not specified in statute. Some workgroup members raised concerns about the potential for commercial insurers and Medicaid Managed Care (MMC) plans to reimburse telehealth encounters at a lower rate than payment for an in-person visit.

In addition to rules specified in the Telehealth Parity Law, three state agencies have issued, or plan to issue, regulations and/or policies governing the use of telehealth. Though at the time of the Workgroup discussions on the topic OMH was the only agency with telehealth regulations promulgated, OASAS and OPWDD expressed intention to license or certify providers who have pursued, or wish to pursue, telehealth arrangements to deliver care. Since completion of the Workgroup meetings, OASAS has since enacted regulations. Though consistent in intent, providers expressed concerned that varying regulations, rules, and policies issued by state agencies create confusion for providers using telehealth, particularly when telehealth arrangements span across settings licensed by different agencies.

IV. Workgroup Recommendations:

1. <u>Allow for reimbursement of telehealth encounters that originate from wherever the patient is located.</u>

   - Remove restrictions on the originating site definition in PHL 2999-cc (3). In the existing statute, originating sites are limited to clinical settings, or to the patient's place of residence when in receipt of remote patient monitoring. By removing restrictions on the originating site definition, flexibility will be allowed for Medicaid reimbursement of telehealth interactions that occur wherever a patient is located.

2. Expand the list of practitioner types included in the definition of telehealth provider in PHL 2999-cc (2).

   - Credentialed Alcoholism and Substance Abuse Counselors (CASACs) and Early Intervention Program providers are not currently included in the list of telehealth providers eligible for Medicaid reimbursement, but can provide valuable services to clients through telepractice. As the use of telehealth grows, there may be other provider types that are not currently included in the statutory definition that may wish to deliver services using telehealth.

   - Amend the telehealth provider definition in PHL 2999-cc (2) to include CASACs and Early Intervention Program Providers. Include an amendment to allow regulatory agencies the flexibility to add additional telehealth providers by regulation.

3. Allow for flexibility to implement and reimburse innovative telehealth delivery models that fall outside of the statutory framework outlined in PHL Article 29-g.

   - Federal regulation 42 CFR 438(3)(e) allows the use of cost-effective alternative services (referred to as "in lieu of services") and enables MMC plans to offer services to members that were not previously included in the MMC benefit package as a Medicaid State Plan service. In this way, services delivered via telehealth using modalities (for example, by telephone) and/or delivered in settings (such as a patient's home) not included in PHL Article 29-g, may be reimbursed.

4. Provide guidance to facilitate Medicaid reimbursement of services delivered via telehealth.

   - The Medicaid Program last issued policy and billing guidance for telemedicine reimbursement in March 2015, prior to full implementation of the Telehealth Parity Law. New detailed billing guidance is needed to inform Medicaid providers about coverage requirements and new billing processes. The updated guidance should include details on the expanded definitions of originating and hub sites, as well as obtaining reimbursement for remote patient monitoring and store-and-forward encounters, two telehealth modalities that were not previously covered by Medicaid.

5. Eliminate multiple co-payments for a single telehealth encounter for Medicaid patients.

   - There are few type of encounters that require a Medicaid co-payment. The issue of multiple co-payments for a single telehealth encounter may apply to a Medicaid FFS Article 28 clinic originating site utilizing telehealth with an Article 28 clinic distant site. Co-payments are not charged for Medicaid FFS doctor's office visits and in Medicaid Managed Care (except for pharmacy). There are also many excluded populations who are not required to pay a Medicaid co-payment, such as pregnant

women. Therefore, the issue of multiple co-payments for a single Medicaid encounter should not be a broad problem, but should be addressed by implementing eMedNY system changes to eliminate multiple co-payments for a single telehealth encounter when the patient is at an Article 28 originating site and the telehealth provider is at an Article 28 distant site.

- Work with DFS to identify how to address multiple co-payments associated with commercial insurers.

6. Issue inter-agency guidance related to use of telehealth in the delivery of health care.

   - New York State regulatory agencies are in varying stages of implementation with regulations, rules and policies related to the use of telehealth in the delivery of care. To the extent possible, agencies should align and streamline regulations and policies, and ensure that the language used is consistent across agencies. Each agency will retain the authority granted through legislation to establish regulations, policies, and guidance regarding the use of telehealth as a mechanism for delivering services within the population of individuals that they serve, as applicability of this delivery method may vary. As regulations are finalized and implemented, inter-agency guidance will be needed to clarify distinctions between the agencies' rules and to address specific nuances relative to use of telehealth in the various settings and with the patient populations served by those agencies.

7. Reconvene stakeholders to continue discussion and problem-solving on telehealth implementation barriers.

   - Stakeholders participating in the RMI workgroup were highly engaged and eager to address telehealth-related barriers. A number of barriers were raised, including reimbursement parity, liability, interstate licensure, credentialing, and technology concerns, which were not fully addressed through this round of the RMI workgroup meetings.

V. Next Steps:

1. DOH will expand the list of eligible originating sites in PHL§ 2999-cc (3) to include reimbursement for telehealth services provided anywhere the patient is located, for all telehealth modalities included in the definition of telehealth in PHL§ 2999-cc (4).

   - **Article VII language introduced with the 2018-19 Executive Budget would implement this recommendation**.[14]

[14] Executive Budget Health and Mental Hygiene Article VII: Subpart C of Part S of S.7507/A.9507

2. OMH will modify and expand existing regulations on telepsychiatry services to "telemental health services" (Title 14 NYCRR Part 596) to add additional mental health practitioner types, requirements about interactive telecommunication systems and recordkeeping.

3. DOH will amend the telehealth provider definition in PHL 2999-cc (2) to include CASACs and Early Intervention Program providers. Include an amendment to allow regulatory agencies the flexibility to add additional telehealth providers by regulation.

   - **Article VII language introduced with the 2018-19 Executive Budget would implement this recommendation.**[15]

4. DOH will release a Medicaid Update article focusing on telehealth reimbursement to inform Medicaid providers about coverage requirements.

5. DOH will implement a process for MMC plans to submit an "in lieu of" services (ILS) Request Form with a Telehealth Innovation Plan to cover telehealth modalities and telehealth services in settings not currently included in PHL Article 29-g.

   - **The Department of Health established an "in lieu of" services (ILS) policy that permits Medicaid Managed Care plans to develop and implement innovative telehealth models. Plans need to document that the models/services are clinically appropriate and cost effective as part of a Telehealth Innovation Plan to request reimbursement for telehealth services. These requests are currently being reviewed by the Department.**[16]

6. OASAS will finalize 14 NYCRR Part 830 ("Designated Services") for OASAS telepractice along with accompanying standards, including guidance for medication-assisted treatment (MAT) using buprenorphine.

   - **OASAS 14 NYCRR Part 830 and the accompanying guidance was adopted as of January 24, 2018.**

7. OPWDD will modify and expand existing regulations to permit for the provision of services delivered via telehealth where appropriate (Title 14 NYCRR Part 679).

[15] Executive Budget Health and Mental Hygiene Article VII: Subpart C of Part S of S.7507/A.9507
[16] "in lieu of" Services Policy:
https://www.health.ny.gov/health_care/managed_care/plans/docs/2017_09_29_in_lieu_of_guidance.pdf

8. New York State will continue inter-agency workgroup meetings (including DOH, OMH, OASAS & OPWDD) focused on collaborating and sharing information on best practices pertaining to the practice of telehealth as well as aligning telehealth regulations, rules and policies. The State will also draft detailed guidance for providers to implement new telehealth regulations following completion of the rule-making process.

VI. Workgroup Meeting Dates:

The workgroup met on September 5, 2017 and September 27, 2017 at the Empire State Plaza in Albany, New York.

VII. Workgroup Members:

Co-Chairpersons

- **Harold Iselin** Greenberg Traurig, representing the Health Plan Association
- **Mary Zelazny** Finger Lakes Community Health
- **Rae Ann Augliera** NYS Department of Health

Members

- **Brenda Bartock** University of Rochester Medical Center
- **Ron Bass** NYS Department of Health
- **Iris Berman** Northwell Health
- **Al Cardillo** Home Care Association of NYS
- **Thomas Check** Healthix
- **Lauri Cole** NYS Council for Community Behavioral Healthcare
- **Carmelita Cruz** NYS Office of Alcoholism and Substance Abuse
- **Stephen Ferrara** The Nurse Practitioner Association of NYS
- **Doug Fish** NYS Department of Health
- **Gary Fitzgerald** Iroquois Healthcare Alliance
- **Peter Fleischut, MD** New York Presbyterian Hospital
- **Jennifer Frontera, MD** NYU Lutheran
- **Christina Galanis** Healthlink NY
- **Cynthia Gordon** Rochester General Health System
- **Bea Grause** Healthcare Association of NYS
- **Ann Griepp, MD** Excellus Blue Cross Blue Shield
- **Michael Hasselberg** University of Rochester Medical Center
- **Robin Hendrix** St. Joseph's Addition Treatment & Recovery
- **Mary Ellen Hennessy** Healthcare Association of NYS
- **Eugene Heslin, MD** NYS Department of Health
- **Jonathan Karmel** NYS Department of Health
- **Jeremy Klemanski** Syracuse Behavioral Health
- **Linda Lambert** NY Chapter of the American College of Physicians

- **Douglas** **Lentivech** NYS Education Department
- **Karen** **Madden** NYS Department of Health
- **Keith** **McCarthy** NYS Office of Mental Health
- **Jane** **McLaughlin** NYS Department of Health
- **Christine** **Nadolny** Medical Society of the State of New York
- **David** **Nardolillo** NYS Office for People With Developmental Disabilities
- **Mahesh** **Nattanmai** NYS Department of Health
- **Laurie** **Neander** Bassett Health Care Network
- **Kimberly** **Noel, MD** SUNY Stonybrook Medical School
- **Brian** **O'Malley** Consumer Directed Personal Assistance Association of NY
- **Sara** **Osborne** NYS Office of Alcoholism and Substance Abuse
- **Lauren** **Pollow** NY Society of Physician Assistants
- **Harvey** **Rosenthal** NY Association of Psychiatric Rehabilitation Services
- **Virginia** **Scott-Adams** NYS Office for People With Developmental Disabilities
- **Dan** **Sheppard** NYS Department of Health
- **Bonnie** **Sloma** People, Inc
- **Amy** **Smith** NYS Office of Mental Health
- **Debra** **Sottolano** NYS Department of Health
- **Jeffrey** **Steigman** Family Service League
- **Zeynep** **Sumer-King** Greater New York Hospital Association
- **Jennifer** **Treacy** NYS Department of Health
- **Lisa** **Ullman** NYS Department of Health
- **Margaret** **Vijayan** NYS Office for People With Developmental Disabilities
- **Salvadore** **Volpe** Medical Society of the State of New York
- **Bridget** **Walsh** Schuyler Center for Analysis and Advocacy
- **Gregory** **Young, MD** NYS Department of Health
- **Corey** **Zeigler** Ft. Drum Regional Health Planning Organization

Off-Campus Emergency Departments:
Improving access to emergency medical services for patients

I. Overview:

Off-Campus Emergency Departments are facilities that provide emergency medical care at a location that is not in a hospital or on a hospital campus. Off-Campus Emergency Departments were originally intended to provide emergency medical services in rural communities where there were no acute care hospitals, and the distance to travel to an emergency department was too great. Most Off-Campus Emergency Departments in rural communities were developed in places where hospitals have closed, typically due to low utilization of inpatient services. Recently, however, Off-Campus Emergency Departments have expanded to urban and suburban areas that have experienced rapid population growth in places where there was no hospital or where specific health outcomes have indicated a need for emergency services.

There are five Off-Campus Emergency Departments currently operating in New York State. Each of these operates in a location where a hospital previously existed. However, New York has not developed specific regulations regarding the need or operation of Off-Campus Emergency Departments, and has not considered licensing them in locations where a hospital was not previously located.

The goal of the workgroup was to determine standards that DOH should use to establish new Off-Campus Emergency Departments in locations where a hospital did not previously exist.

II. Actions to Date:

The Center for Medicare and Medicaid Services (CMS) classifies Off-Campus Emergency Departments as hospital affiliated or independent entities. CMS has specified that hospital affiliated Off-Campus Emergency Departments should be known as Hospital-Sponsored Off-Campus Emergency Departments. Independent entities are referred to as Free-Standing Emergency Departments.

New York State allows for the operation of Hospital-Sponsored Off-Campus Emergency Departments and has relied on CMS regulations and existing state regulations to determine need and govern operations. The specific New York State regulations that govern the ownership and operation of Off-Campus Emergency Departments include Title 10, Section 700.2 and Section 405.19.

The need for Off-Campus Emergency Departments has been assessed using the state regulations that are used to determine the necessity of hospital services as found in Title 10, Section 709.

The New York State Public Health and Health Planning Council (PHHPC) included Off-Campus Emergency Departments as part of a comprehensive review of Ambulatory Care Services and issued recommendations in January 2014. Those recommendations focused on hospital-operated Off-Campus Emergency Departments. The PHHPC specifically recommended that Off-Campus Emergency Department ownership be restricted to hospitals and that non-hospital owned Off-Campus Emergency Departments be prohibited.

There have been six Off-Campus Emergency Departments approved since 2013 in New York State. Five Off-Campus Emergency Departments are currently operational. Each of these facilities is located where full-service hospitals previously existed.

III. Obstacles:

It is anticipated that there will be increased interest among providers to operate Off-Campus or Free-Standing Emergency Departments in places where hospitals have not existed. A methodology to assess the need for these Off-Campus or Free-Standing Emergency Departments does not exist. Additionally, there are no specific regulations pertaining to the operation of Off-Campus or Free-Standing Emergency Departments.

IV. Workgroup Recommendations:

1. New York State should continue to allow only those Off-Campus Emergency Departments affiliated with a hospital or hospital system.

   - There was consensus among members that allowing Off-Campus Emergency Departments not affiliated with hospitals would lead to a lack of integrated care, decreased collaboration with population health initiatives, confusion among the public regarding the nature of services being provided and difficulty in directing resources where they are needed.

   - There also is a concern that independent entities could create destructive competition because they may not be held to the same standards as affiliated Off-Campus Emergency Departments. The federal Emergency Medical Treatment and Labor Act (EMTALA), for example, requires anyone coming to an emergency department to be stabilized and treated, regardless of ability to pay.

2. It is not necessary to create a new need methodology.

   - Current standards for reviews may be used for Off-Campus Emergency Departments without creating a new need methodology. Applicants should demonstrate the need for emergency services, value to the community and the impact on surrounding emergency departments. Flexibility to account for unique local factors should be factored into DOH's decision-making process.

3. Options to ensure sustainability should be explored.

   - Although the current certificate of need review process requires that applicants demonstrate financial feasibility and sustainability, that process may not cover all the financial issues related to operating Off-Campus Emergency Departments, including access to capital resources to invest in technology and a low volume of patients. Workgroup members recommended that DOH consider reimbursement options that take into account the unique financial needs of Off-Campus Emergency Departments.

V. Next Steps:

1. Continue to authorize only those Off-Campus Emergency Departments that are affiliated with a hospital or hospital system.

2. Determine whether the Department should advance a need methodology that considers utilization, geographic access, including a minimum distance from other emergency departments, and the potential impact on other hospital emergency departments or Off-Campus Emergency Departments.

VI. Workgroup Meeting Date:

The workgroup met on October 10, 2017 at the Empire State Plaza in Albany, New York.

VIII. Workgroup Members:

Co-Chairpersons

• **John**	**Remillard**	Elizabethtown Community Hospital
• **Karen**	**Madden**	NYS Department of Health

Members

• **Morris**	**Auster**	Medical Society of the State of New York
• **David**	**Barlas, MD**	NYU Langone Health - Cobble Hill
• **Lee**	**Burns**	NYS Department of Health
• **Carmelita**	**Cruz**	NYS Office of Alcoholism and Substance Abuse Services
• **Paula**	**Fessler**	The Nurse Practitioner Association NYS
• **Gary**	**Fitzgerald**	Iroquois Healthcare Alliance
• **Sylvia**	**Getman**	Adirondack Health Institute
• **Bea**	**Grause**	Healthcare Association of NYS
• **Beverly**	**Grossman**	United Health Group

• **Amy**	**Gutman-Enright, MD**	Health Alliance
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• **David**	**Jackson**	NYS Society of Physician Assistants
• **Ruth**	**Leslie**	NYS Department of Health
• **Eric**	**Mantey**	NYS Department of Health
• **Tracy**	**Raleigh**	NYS Department of Health
• **Peter**	**Robinson**	University of Rochester Medical Center
• **Peter**	**Semczuk, MD**	Montefiore Medical Center
• **Lois**	**Uttley**	MergerWatch
• **Susan**	**Waltman**	Greater New York Hospital Association
• **Gregory**	**Young, MD**	NYS Department of Health

Appendix A: PCI Volume-Mortality Study*

	%	Observed Mortality Rate: Deaths per patient (%)	Estimate	Odds Ratio	P-value
Hospital Volume (# of hospitals)					
< 150 (6)	0.99	1.82	0.0807	1.08	0.64
≥ 150 (57)	99.01	1.15	--	ref	--
Hospital Volume (# of hospitals)					
< 300 (19)	6.95	1.56	0.0967	1.10	0.32
≥ 300 (44)	93.05	1.12	--	ref	--
Hospital Volume (# of hospitals)					
< 400 (23)	9.59	1.55	0.0993	1.10	0.22
≥ 400 (40)	90.41	1.11	--	ref	--

*Based on New York Percutaneous Coronary Interventions (PCI) Registry data (2013-2015)