# REGULATORY FLEXIBILITY GUIDANCE FOR DELIVERY SYSTEM REFORM INCENTIVE PAYMENT (DSRIP) PROGRAM PERFORMING PROVIDER SYSTEMS

**Presented to the Health Planning Committee of the Public Health and Health Planning Council**

**September 17, 2014**

# Overview

- The purpose of today's meeting is to provide the PHHPC Planning Committee with information about the *DSRIP Regulatory Flexibility Guidance* document, which will be released on Thursday.

- The Guidance Document reflects an analysis and synthesis of substantial stakeholder input provided by:
  - DSRIP applicants as part of their Design Grant applications; and,
  - Reviewing letters from and meeting with stakeholders to gain a better understanding of where regulatory relief may be needed in order to help facilitate implementation of DSRIP projects.

# Overview (continued)

- The Guidance will:
  - identify regulatory areas and specific regulations for which the State will or will not entertain waiver requests;
  - identify agency policies that will be waived; and,
  - note that, in some cases, waivers may not be available due to federal rules or state statute, and if the agencies will pursue changes.

- The document will be posted online, and refined and expanded on an ongoing basis as the process of PPS formation and project development yields greater specificity with respect to areas where regulatory waivers may be beneficial and appropriate.

# BACKGROUND

# DSRIP AND THE CAPITAL RESTRUCTURING FINANCING PROGRAM

# Delivery System Reform Incentive Payment (DSRIP) Program

The Delivery System Reform Incentive Payment (DSRIP) Program, a component of the $8 billion Medicaid Waiver Amendment, will reinvest $6.42 billion for the purpose of:

- transforming the State's health care safety net system;
- reducing avoidable hospital use and achieving other improvements in health and public health; and
- promoting the sustainability of delivery system transformation by leveraging managed care payment reform.

# DSRIP Projects

PPSs will collaborate on DSRIP project in four domains:

- Overall Project Progress Projects (Domain 1);
- System Transformation Projects (Domain 2);
- Clinical Improvement Projects (Domain 3); and
- Population-Wide Projects (Domain 4).

# Key DSRIP Dates

- September 29, 2014: Draft DSRIP Project Plan application issued for public comment
- November 14, 2014: Final application released
- December 16, 2014: Applications due
- January 2015: Public comment due on applications
- March 2015: DSRIP Project Plan awards made
- April 1, 2015: Start of Year 1 of DSRIP implementation

# Capital Restructuring Financing Program

- The State will award up to $1.2 billion to support capital projects that will help strengthen and promote access to essential health services.

- Eligible providers include general hospitals, residential health care facilities, diagnostic and treatment centers and clinics licensed pursuant to the Public Health Law (PHL) or the Mental Hygiene Law (MHL), assisted living providers, primary care providers, and PHL Article 36 home care providers.

- The majority of the capital funding will be allocated for projects aligned with the DSRIP Program; applications for capital funding will be made along with DSRIP applications.

# REGULATORY WAIVER AUTHORITY

# Regulatory Waiver Authority

PHL § 2807(20)(e) and (21)(e) authorize the waiver of regulatory requirements for DSRIP projects and capital projects that are associated with DSRIP projects by:

- the Department of Health (DOH),
- the Office of Mental Health (OMH),
- the Office of Alcoholism and Substance Abuse Services (OASAS), and
- the Office for People With Developmental Disabilities (OPWDD)

A waiver may be issued:

- as necessary to allow applicants to avoid duplication of requirements and to allow the efficient implementation of the proposed projects;
- only if the waiver would not jeopardize patient safety; and
- only for the life of the project.

# REGULATORY WAIVER PROCESS

# Waiver Requests

Waiver requests will be included in the DSRIP Project Plan application and will require submission of information such as:

- the regulation for which a waiver is being requested;
- the components of the Project Plan affected by the regulation;
- the reason the waiver is needed, including an explanation of how a waiver will assist in implementation of the Project Plan and reaching better health outcomes; and
- an explanation as to why the waiver would not negatively impact patient safety.

# Waiver Conditions

In approving requests for waivers, DOH, OMH, OASAS or OPWDD may require the applicant to:

- submit policies and procedures designed to mitigate any risk to persons or providers affected by the waiver;
- train appropriate staff on the policies and procedures;
- monitor implementation to ensure adherence to the policies and procedures; and
- evaluate the effectiveness of the policies and procedures in mitigating risk.

If these standards are not satisfied, the State may decline to approve the waiver or, if it has already approved the waiver, may withdraw its approval and require the applicant to maintain compliance with the regulations.

# Waiver Tracking and Reporting

- The agencies will establish a process to track waivers by provider and facility to ensure that surveyors are aware of approved waivers.

- If the survey team determines that the provider has failed to comply with any conditions under which a waiver was granted, the waiver is subject to revocation and the provider could be subject to citations for the underlying regulatory standards.

- PHL § 2807(20)(e) and (21)(e) provide that the agencies must describe any regulatory relief granted, including each regulation waived and the project to which it relates, in quarterly Medicaid Redesign Team/DSRIP reports provided to the Legislature and made public pursuant to PHL § 2807(20)(c) and (21)(b).

# AREAS OF GUIDANCE

# PPS FORMATION ISSUES

# PPS Formation

- **Antitrust -** PHL § 2807(20)(e) and (21)(e) do not give the agencies the ability to waive federal and state antitrust laws. DOH is in the process of issuing two sets of regulations pursuant to state laws that offer protections from antitrust liability in certain circumstances:
  - 10 NYCRR Subpart 83-1 (Certificates of Public Advantage); and
  - 10 NYCRR Part 1003 (Accountable Care Organizations).

  PPSs can requests COPAs or ACO certificates of authority when applying for DSRIP Project Grants.

- **Corporate Practice of Medicine** - The prohibition on the corporate practice of medicine is a statutory doctrine and cannot be waived under PHL § 2807(20)(e) and (21)(e); however, the ACO regulations permit a corporate structure provided ACOs meet all other regulatory requirements.

- **Fraud and Abuse Statutes** – Statutory provisions cannot be waived; the ACO regulations define several “safe harbors” that will apply provided ACOs meet all other regulatory requirements.

# INTEGRATED SERVICES

# Integration of Services (One Provider)

- PPSs are likely to request regulatory waivers which will assist them in their efforts to integrate primary care and behavioral health services.
- Generally, to offer both primary care and behavioral health services (meaning mental health and/or substance use disorder services), a provider must be licensed or certified by more than one agency.
- To facilitate the integration of primary care and behavioral health services, DOH, OMH and OASAS will permit DSRIP providers to offer primary care services to individuals receiving behavioral health services and vice versa without additional licensures.
- Providers will have to be in good standing under a single license or certification.
- No regulatory changes are needed to achieve this.

# Shared Space (Two or More Providers)

- PPSs are likely to be interested in pursuing waivers so that multiple providers could share the same licensed physical space.

- To facilitate the integration of services, DOH, OMH and OASAS will allow shared space pursuant to an approved written plan, consistent with federal rules and provided that all entities sharing space remain accountable for how it is utilized.

- When tax-exempt bonds are used to finance construction of a non-profit health facility, the sharing of that facility's space will necessitate approval of the financing authority/lender. Providers should consult bond counsel.

# CERTIFICATE OF NEED

# Changes in Capacity or Services

- Until recently, a general hospital or diagnostic and treatment center (D&TC) would need to submit a CON application if it wanted to add to or remove from its operating certificate any one of up to 60 types of outpatient services.

- In July 2014, DOH announced that, based upon a recommendation of PHHPC, it has reduced the number of outpatient services that trigger CON review to 22.

- To afford additional flexibility as necessary to promote efficient implementation of DSRIP projects and pursuant to its authority under PHL § 2807(20)(e) and (21)(e), DOH will entertain requests for waivers of CON regulations pertaining to proposed changes in capacity or the type of services provided.

- For example, DOH would consider granting waivers of 10 NYCRR § 401.3 pertaining to changes in physical plant, bed capacity, and the extent and kind of services provided.

# Need Methodologies

- DOH will entertain requests for waivers of need methodologies set forth in 10 NYCRR Parts 670, 700 and 709 (medical facilities).

- DOH will entertain requests for waivers of 10 NYCRR Part 760 to permit certified home health agencies (CHHAs) to extend their geographic service areas within PPSs.

- Requests to extend the service areas of licensed home care services agencies (LHCSAs) within PPSs can be made under existing regulatory authority; no waivers are needed.

- DOH will entertain requests for waivers of need methodologies set forth in 10 NYCRR Part 790 (hospice). In addition, in conjunction with a PHHPC recommendation, DOH is already in the process of reviewing the hospice need methodology to determine whether amendments to the regulations are necessary.

# OWNERSHIP AND MANAGEMENT

# Ownership and Management

DOH will entertain requests to waive regulations that could serve as obstacles to the organization and structure of a PPS under its approved Project Plan, including:

- 10 NYCRR § 405.1(c) (requiring establishment for persons or entities exercising active parent powers);
- 10 NYCRR § 600.9(c) (prohibiting participation in income or revenue by individuals or entities without establishment approval); and
- 10 NYCRR §§ 405.3(f) and 600.9(d) (prohibiting a hospital from contracting for management services absent DOH approval).

# Construction Standards

- DOH regulations require health care facilities to be maintained in compliance with the National Fire Protection Association Life and Safety Code, the Facility Guidelines Institute's (FGI) Guidelines for Design and Construction of Hospitals and Outpatient Facilities, the FGI's Guidelines for Design and Construction of Residential Health, Care, and Support Facilities and DOH-specific rules for the design of facilities.

- DOH will entertain requests for waivers of these regulations to the extent patient safety concerns are not implicated and the waivers are consistent with federal rules.

- Pre-opening surveys are required after completion of a construction project pursuant to 10 NYCRR § 710.9. They cannot be waived under federal requirements and could implicate patient safety, but DOH will expedite reviews where possible.

# OPERATING STANDARDS

# Admission, Transfer and Discharge

- DOH will entertain requests to waive regulations that could serve as obstacles to the management of patients within a PPS under its approved Project Plan, to the extent consistent with federal requirements and assuming medical appropriateness, including:
  - 10 NYCRR § 400.9 (governing transfer and affiliation agreements);
  - 10 NYCRR §§ 400.11 and 700.3 (governing assessment of long term care patients); and
  - 10 NYCRR § 405.9(f)(7) (prohibiting hospital from transferring or discharging patients based on source of payment).
- 18 NYCRR § 505.20 (providing that no Medicaid reimbursement is available if a patient is admitted because an appropriate placement at a lower level of care was not available) cannot be waived due to federal provisions.

# Observation Services

- 10 NYCRR § 405.19(g) establishes standards for the provision of hospital observation services consistent with federal Medicare requirements.

- PPSs are likely to be interested in pursuing waivers of DOH limits on the number of observation beds to 5 percent of a hospital's certified bed capacity, requirements that observation units be in a distinct physical space, and approval for the construction of such units.

- Pursuant to its authority under PHL § 2807(20)(e) and (21)(e), DOH, OMH and OASAS will entertain requests for waivers of such regulations on a case-by-case basis, to the extent such waivers are not inconsistent with any applicable federal requirements.

# Practitioner Credentialing

- PPSs are likely to be interested in simplifying credentialing processes for all practitioners who care for patients throughout the PPS.

- Pursuant to its authority under PHL § 2807(20)(e) and (21)(e) and subject to the general conditions discussed above, DOH will entertain requests for waivers of 10 NYCRR §§ 405.2 and 405.4 pertaining to credentialing.

# Home Visits

- DOH will entertain requests for waivers of 10 NYCRR § 401.2(b), which provides that an operator may use an operating certificate only for the designated site of operation. This would allow individuals with chronic illnesses to be visited at home by practitioners employed by general hospital outpatient departments and diagnostic and treatment clinics.

- However, to permit Medicaid reimbursement for such services, DOH will amend 10 NYCRR §§ 86-4.9, 86-8.14 and 401.2, and submit to CMS an amendment to New York's Medicaid State Plan.

# Telemedicine and Telehealth

- PPSs are likely to request regulatory waivers in order to facilitate their ability to carry out DSRIP projects involving telemedicine and/or telehealth.

- Authorizing reimbursement for telemedicine/telehealth beyond existing provisions cannot be accomplished through regulatory waivers, as there are no applicable regulations.

- DOH will explore this further.

# INFORMATION SHARING

# Information Sharing

- The Health Insurance Portability and Accountability Act (HIPAA) allows providers to disclose patient information to other providers for treatment, payment or health care operations.

- However, other provisions of HIPAA, as well as other federal and state statutory provisions, contain confidentiality provisions that will restrict patient information sharing within a PPS.

- As a result, waiver opportunities are limited, but DOH, OMH and OASAS will coordinate on the development of a model consent form for use by PPS providers that would cover all forms of patient information exchanged by providers.

# WORKFORCE FLEXIBILITY

# Home Care Orders by NPs and PAs

- PPSs are likely to be interested in using Physician Assistants (PAs) to issue orders related to the provision of home health care by LHCSAs.
- To allow PAs to sign home care orders for LHCSAs, DOH will pursue regulatory changes; this cannot be accomplished through a waiver.
- PPSs also are likely to be interested in broadening home care ordering authority to Nurse Practitioners (NPs) and PAs to issue and sign orders for home care by CHHAs.
- Federal regulations do not allow nurse practitioners or physician assistants to sign medical orders for CHHAs and LTHHCPs. Accordingly, no waiver is available pursuant to DOH's authority under PHL § 2807(20)(e) and (21)(e).

# Nurse-Driven Protocols

- Under current NYS law, a physician or certified Nurse Practitioner (NP) can prescribe, and nurses can implement, standing orders for four categories of "regimens": administering immunizations; emergency treatment of anaphylaxis; administering purified protein derivative (PPD) tests; and administering HIV tests. Under federal regulation, NPs can prescribe and nurses can implement a more broad range of regimens.

- PPSs are likely to be interested in pursuing waivers to authorize widespread use of nurse-driven protocols, consistent with federal/national standards and utilizing evidence-based strategies for disease management.

- No regulatory waiver is available pursuant to PHL § 2807(20)(e) and (21)(e), as statutory changes would be needed. DOH will consider developing a legislative proposal to achieve this.

# Advanced Home Health Aides

- The Governor has previously submitted legislation to establish a classification of Advanced Home Health Aides who would be authorized to administer medication and carry out other advanced tasks.

- DOH recently convened a workgroup to provide guidance on advanced tasks that could be performed by home health aides in home care and hospice settings with appropriate training and supervision, if authorized as an exemption to the Nurse Practice Act in the Education Law.

- DOH cannot authorize Advanced Home Health Aides pursuant to its authority under PHL § 2807(20)(e) and (21)(e) without statutory changes. However, the recommendations of the Advanced Home Health Aide Workgroup will be used in development of a future legislative proposal.

# Emergency Medical Services

- PHL Article 30 provides that a certified emergency medical services (EMS) provider may only care for a patient in response to an emergency. PPSs are likely to be interested in pursuing regulatory waivers if it could help allow emergency medical technicians (EMTs) and paramedics to provide non-emergent Community Paramedicine. This is a statutory issue and cannot be waived; however, DOH will consider recommending legislative changes.

- PPSs are likely to be interested in pursuing regulatory waivers to enable EMS providers to transport patients to alternate destinations for non-acute situations. PHL § 3010(3) already permits EMS to allow transport of patients to alternate destinations for non-acute situations, as allowed by the ambulance service's operating certificate. No regulatory waiver relief is necessary.