REGULATORY FLEXIBILITY GUIDANCE FOR PERFORMING PROVIDER SYSTEMS

September 18, 2014

I. INTRODUCTION

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) are issuing this guidance to Performing Provider Systems (PPSs) interested in seeking regulatory waivers in connection with the Delivery System Reform Incentive Payment (DSRIP) Program and the Capital Restructuring Financing Program, pursuant to Public Health Law (PHL) § 2807(20)(e) and (21)(e).

As PPS plans become more concrete and it appears that there are additional areas where waivers may be appropriate, the agencies will refine this document accordingly.

A. DSRIP

DSRIP, a component of the $8 billion Medicaid Waiver Amendment, will reinvest $6.42 billion over the next five years, beginning April 1, 2015, 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 providers will collaborate in the submission of DSRIP Project Plan applications as part of PPSs.

PPSs will collaborate on DSRIP projects 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).

Each PPS will employ multiple projects both to transform health care delivery as well as to address the broad needs of the population that the performing provider system serves. Each project will be developed into a specific set of focused milestones and metrics that will be part of the PPS's DSRIP Project Plan.

Earlier this year, the State awarded Design Grant funds that will assist emerging PPSs in designing comprehensive DSRIP Project Plans. On September 29, 2014, DOH will issue, for public comment, the draft DSRIP

Project Plan application, which will be finalized and released on November 14, 2014. Applications will be due on December 16, 2014, with public comment on the applications due in January 2015. Awards will be made in March 2015, and PPSs will start Year 1 of DSRIP implementation on April 1, 2015.

B. Capital Restructuring Financing Program

Pursuant to PHL § 2825, 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 PHL or the Mental Hygiene Law, 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 and applications for capital funding will be submitted along with DSRIP applications.

C. Regulatory Waiver Authority

PHL § 2807(20)(e) and (21)(e) authorizes DOH, OMH, OASAS and OPWDD to waive certain regulatory requirements for DSRIP projects and capital projects that are associated with DSRIP projects. The agencies are authorized to grant such waivers as necessary, consistent with applicable law, to allow applicants to avoid duplication of requirements and to allow the efficient implementation of the proposed projects. However, the agencies may not waive regulations pertaining to patient safety nor waive regulations if such waiver would risk patient safety. Any waivers granted under this authority may not exceed the life of the project or such shorter time periods as the authorizing commissioner may determine.

In accordance with the statutory provisions, waivers must be project-specific and do not automatically apply to all partners within a PPS.
In addition, although waivers are intended to facilitate DSRIP Project Plans and are available only for the duration and scope of such plans, they may not be used to establish dual systems of care. Therefore, although DSRIP is a Medicaid initiative, it would be expected that quality improvements and clinical innovations achieved under a Project Plan would be made available to all of a PPS provider's patients.

In addition, only state regulations can be waived – not federal statute or federal regulations or state statute. However, the agencies will consider proposing changes to federal statute or regulations or state statute, as appropriate to facilitate improvements in and sustainability of delivery system transformation. In addition, the agencies will look for opportunities

to pursue regulatory reforms on a more permanent basis, which would apply outside of DSRIP Project Plans.

II. REGULATORY WAIVER PROCESS

As noted, requests for regulatory waivers will be submitted in conjunction with the DSRIP Project Plan application. However, if a PPS later identifies the need for a waiver, a request can be made at that time.

A. Waiver Requests

The DSRIP Project Plan application will include additional detail about the information that must be submitted in support of waiver requests. The type of information that will be requested includes:

- The regulation for which a waiver is being requested;
- Components of the project plan affected by the regulation;
- The reason(s) the waiver is necessary, including an explanation of how a waiver will assist in implementation of the project plan and reaching better health outcomes;
- A description of proposed alternatives to compliance with the regulatory standard for which the waiver is sought; and
- A description of the impact that the waiver and implementation of approved alternatives would have on safety.

B. Waiver Conditions

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

- submit policies and procedures designed to mitigate the 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.

C. Waiver Tracking and Surveillance

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.

D. Waiver Reporting

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).

III. AREAS OF GUIDANCE

A. PPS FORMATION

1. Antitrust

PPSs are likely to be interested in any regulatory flexibility that would address federal and state antitrust concerns and facilitate their ability to move forward under DSRIP. While 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 regulations for Certificates of Public Advantage (COPA) and Accountable Care Organizations (ACOs) pursuant to state laws that offer protections from antitrust liability in certain circumstances. PPSs will be able request that the State provide antitrust immunity through a COPA or an ACO certificate of authority when submitting a DSRIP Project Plan application.

a. Certificates of Public Advantage

PHL Article 29-F sets forth the State's policy of encouraging appropriate collaborative arrangements among health care providers who might otherwise be competitors, if the benefits

of such arrangements outweigh any disadvantages likely to result from a reduction of competition. The statute requires DOH to establish a regulatory structure allowing it to engage in active state supervision as necessary to promote state action immunity under state and federal antitrust laws.

DOH has proposed regulations, 10 NYCRR Subpart 83-1, establishing a process for entities to obtain a COPA pursuant to PHL Article 29-F. A COPA will be granted if it appears that the benefits of the collaborative activity outweigh any disadvantages attributable to their anticompetitive effects, and would have the effect of protecting the arrangement from antitrust liability. In making that determination, DOH will consult with the Office of the Attorney General and, where appropriate, OMH, OASAS and OPWDD, and will seek the recommendation of the Public Health and Health Planning Council. Ongoing, active supervision will be conducted to ensure that the benefits of the collaborative activity continue to outweigh the anticompetitive effects thereof.

The proposed regulations were initially published in the State Register on September 18, 2013, and have been revised in light of public comments received. A Notice of Revised Rulemaking was published in the August 27, 2014 State Register. The revised regulations will take effect upon publication of a Notice of Adoption.

b. Accountable Care Organizations

PHL Article 29-E requires DOH to establish a process for the issuance of certificates of authority for ACOs. An ACO is a voluntary organization of clinically integrated health care providers that work together to provide, manage, and coordinate health care for a defined population, has a mechanism for shared governance and the ability to negotiate, receive, and distribute payments, and is accountable for the quality, cost, and delivery of health care to the ACO's patients. Obtaining a certificate of authority will allow an ACO to take advantage of certain "safe harbors" offering protection from antitrust liability, prohibitions on referral, and limitations on the corporate practice of medicine. Proposed regulations, 10 NYCRR Part 1003, will be published in the State Register in the near future.

2. Corporate Practice of Medicine

PPSs are likely to be interested in making sure that the application of the corporate practice of medicine doctrine does not prevent them from organizing a PPS as contemplated under DSRIP.

However, as noted above, PPSs can seek certificates of authority for ACOs, and under the proposed regulations to be issued, the provision of ACO services shall not be considered the practice of a profession under Title 8 of the Education Law.

3. Fraud and Abuse Statutes

Various federal and state statutory provisions prohibit fee-splitting and revenue sharing, such as the federal Anti-Kickback statute and the prohibition against physician self-referrals in the federal Stark Law and PHL § 238-a. PPSs are likely to be interested in making sure that these types of provisions do not prevent them from distributing funds within the PPS in the manner contemplated under DSRIP.

The ACO regulations define several “safe harbors” that will apply if all other regulatory requirements are satisfied. PPSs can request ACO certificates of authority when applying for DSRIP Project Grants. No regulatory waiver is available.

B. INTEGRATED SERVICES

1. 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, unless they fall under the applicable “Licensure Threshold.”

a. Primary Care Provider Offering Mental Health Services

Currently, a provider licensed under PHL Article 28 and offering primary care services – meaning a general hospital outpatient department or a diagnostic and treatment center (“primary care provider”) – and which has more than 2,000

total visits per year must obtain Article 31 licensure by OMH if it provides more than 10,000 annual visits for mental health services or more than 30 percent of its total annual visits are for mental health services, whichever is higher.

b. Primary Care Provider Offering Substance Use Disorder Services

Currently, a primary care provider may not provide substance use disorder services without Article 32 certification by OASAS.

c. Behavioral Health Services Provider Offering Primary Care Services

Currently, a provider licensed by OMH under MHL Article 31 to provide outpatient mental health services or certified by OASAS under MHL Article 32 to provide outpatient substance use disorder services must obtain PHL Article 28 licensure by DOH if more than 5 percent of total visits are for primary care services or if any visits are for dental services.

d. Mental Health Services Provider Offering Substance Use Disorder Services and Substance Use Disorder Services Provider Offering Mental Health Services

Programs licensed or certified by either OMH or OASAS are able to integrate mental health and substance use disorder services with certain limitations pursuant to a Memorandum of Agreement between the two state agencies.

In order to facilitate the integration of primary care and behavioral health services, DOH, OMH and OASAS are working to integrate and simplify the licensure process for providers that exceed the Licensure Thresholds, which would otherwise need to be licensed by more than one agency. The agencies are working on regulatory changes to achieve this.

To facilitate the ability of PPSs to comprehensively address the health and behavioral health concerns of patients, DOH, OMH and OASAS will permit DSRIP providers to offer primary care and behavioral health services under a single license or certification issued pursuant to the Public Health Law or the Mental Hygiene Law. The state agency that issued the license or certification will be responsible for oversight of the provider. Oversight will be based on compliance with the licensing or certifying agency's

standards and the enumerated scope of the particular DSRIP project. To obtain this authority, providers will have to demonstrate that they are in good standing, have adequate staffing plans and sufficient space, and their practitioners will act within their respective scope of practice.

2. 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.

Currently, OMH regulations allow Article 31 providers to share space with any other provider licensed or certified by OMH, OASAS or DOH, pursuant to a written plan approved by OMH. Similarly, OASAS regulations allow Article 32 providers to share space with any other providers licensed or certified by OASAS, OMH or DOH, to share space pursuant to a plan by OASAS.

Under federal regulations, general hospitals, nursing homes, and clinics offering End Stage Renal Disease (ESRD) service may not share space with any other providers. Further, diagnostic and treatment centers with federal designations such as ambulatory surgery centers and FQHCs are prohibited by federal law from mixing functions and operations in a common space during concurrent or overlapping hours of operations.

In addition to the federal rules, pursuant to 10 NYCRR 401.2(b), an operating certificate shall be used only by the established operator for the designated site of operation, except that the commissioner may permit the established operator to operate at an alternate or additional site approved by the commissioner on a temporary basis in an emergency. Currently, DOH requires Article 28 facilities be separate and distinct from other provider types (e.g., the facility must be a separate, identifiable entity and must be physically, administratively and financially independent and distinct from other operations of any other provider or health facility).

Under 10 NYCRR 401.3(d), the governing authority or operator of a medical facility to whom a current operating certificate has been issued is prohibited from leasing or subletting all or a portion of the facility, unless such facility, its operation, and the service performed conform to and comply with other pertinent provisions required of medical facilities.

To facilitate the integration of services, DOH, OMH and OASAS will allow shared space pursuant to an approved written plan,

consistent with federal rules. However, all licensed providers will be held accountable for complying with all applicable regulatory standards. Potentially, some of these standards, particularly those pertaining to physical plant requirements, could be waived under PHL § 2807(20)(e) and (21)(e), consistent with federal rules, as discussed further below.

It should be noted that 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 and providers should consult bond counsel.

C. CERTIFICATE OF NEED

The Certificate of Need (CON) program governs the establishment, ownership, construction, renovation and changes in service of specific types of health care facilities, including:

- General hospitals, nursing homes and clinics (PHL § 2801-a);
- Certified home health agencies (CHHAs) (PHL § 3605); and
- Hospices (PHL § 4004).

CON approval is needed from PHHPC and/or DOH prior to:

- Establishing and/or constructing new facilities, agencies, programs or hospices;
- Renovating existing facilities, agencies, programs or hospices;
- Acquiring major medical equipment;
- Adding or deleting services;
- Changing ownership of facilities, agencies, programs or hospices; and
- Modifying service areas for agencies or hospices.

1. Projects Requiring CON Review

PPSs are likely to be interested in pursuing waivers to exempt established providers from having to undergo the CON process for proposed changes in capacity or the type of services provided, when such changes are sought in connection with DSRIP projects.

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. Based upon a recommendation of PHHPC, DOH has reduced the number of outpatient services that trigger review to 22.

To afford additional flexibility as necessary to promote efficient implementation of DSRIP projects, DOH will entertain requests for waivers of CON regulations pursuant to its authority under PHL § 2807(20)(e) and (21)(e). 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).

2. Need Methodology

Various DOH regulatory provisions set forth the methodologies used to determine public need as part of the establishment and construction processes. These include 10 NYCRR Parts 670 (medical facility establishment), 700 and 709 (medical facility construction), 760 (CHHA establishment) and 790 (hospice).

PPSs are likely to be interested in pursuing waivers of such regulations in order to facilitate implementation of DSRIP project plans.

a. Medical Facilities

PPSs are likely to be interested in pursuing waivers of 10 NYCRR Part 670, 700 or 709 in order to facilitate PPS activities. For example, a PPS may assert that it is necessary to obtain an item of medical equipment in order to advance specific clinical objectives under one of its DSRIP projects. In such a case, the approval of that project plan should substitute for a separate public need analysis, and DOH therefore could waive the regulatory methodology.

Pursuant to its authority under PHL § 2807(20)(e) and (21)(e), DOH will entertain requests for waivers of 10 NYCRR Parts 670, 700 and 709 on a case by case basis, and will grant them to the extent necessary for a PPS to carry out approved DSRIP project plan activities.

b. CHHAs

PPSs are likely to be interested in pursuing waivers of 10 NYCRR Part 760 to allow a CHHA that is a member of a PPS to extend its service area beyond that reflected in its operating certificate, so it can provide services throughout the geographic area served by the PPS.

DOH will entertain requests for waiver of the need methodology for CHHAs in order to allow a CHHA to provide services outside of the service area reflected in its operating certificate for the purpose of carrying out approved DSRIP project plan activities.

c. LHCSAs

PPSs are likely to be interested in pursuing waivers of applicable regulations to allow a Licensed Home Care Services Agency (LHCSA) that is a member of a PPS to extend its service area beyond its approved service area so it can provide services throughout the geographic area served by the PPS.

While establishment of LHCSAs requires DOH approval, DOH regulations do not set forth a formal need methodology for their establishment. Therefore, there are no regulations to be waived in order to allow expansion of a LHCSA's service area. However, LHCSAs may expand their approved service areas with DOH approval, and DOH will approve such requests as necessary to allow LHCSAs to carry out approved DSRIP project plan activities.

d. Hospice

PPSs are likely to be interested in pursuing waivers of the hospice need methodology set forth in 10 NYCRR Part 790 in order to expand the geographic areas in which they are authorized to operate.

DOH will entertain requests for waivers of the relevant sections of 10 NYCRR Part 790 on a case by case basis, and will grant them to the extent necessary for a PPS to carry out approved DSRIP project plan activities.

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.

3. Ownership and Management

a. Active Parent

10 NYCRR § 405.1(c) provides that "any person . . . or other entity with the authority to operate a hospital must be approved for establishment by the [Public Health and Health Planning Council] unless otherwise permitted to operate by the Public Health Law . . ." It defines an "operator" of a hospital as an entity with "decision-making authority" over any of the active parent powers listed under 405.1(c).

PPSs are likely to be interested in waiving this provision to the extent it restricts the PPS lead agency or other providers within the PPS from establishing an internal structure for purposes of implementing their Project Plans. Pursuant to its authority under PHL § 2807(20)(e) and (21)(e), DOH will entertain requests for waivers of 10 NYCRR § 405.1(c).

b. Revenue Sharing

10 NYCRR § 600.9(c) provides that "an individual, partnership or corporation which has not received establishment approval may not participate in the total gross income or net revenue of a medical facility."

PPSs are likely to be interested in pursuing waivers of this provision in order to permit distribution of DSRIP proceeds between PPS established and non-established providers sharing a patient population.

Pursuant to its authority under PHL § 2807(20)(e) and (21)(e), DOH will entertain requests for waivers of 10 NYCRR § 600.9(c).

c. Management Contracts

10 NYCRR § 600.9(d) provides that the governing authority of a hospital may not contract for management services with a party which has not received establishment approval, except as permitted under 10 NYCRR § 405.3. 10 NYCRR § 403.5(f) requires DOH approval of management contracts, under which the governing body of a general hospital contracts with an entity to assume the day-to-day operations of the entire facility or a unit of the facility.

PPSs are likely to be interested in waivers of these regulations so that PPSs can move quickly to carry out their project plans.

Pursuant to its authority under PHL § 2807(20)(e) and (21)(e), DOH will entertain requests for waivers of 10 NYCRR §§ 403.5(f) and 600.9(d) on a case by case basis, and will grant them to the extent necessary for a PPS to carry out the collaborative activities required under DSRIP.

4. Construction Standards

PHL § 2802 requires the Commissioner's approval for construction of a hospital; PHHPC review is required in some cases but not others, as set forth in regulation. 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 the Design and Construction of Residential Health, Care, and Support Facilities and DOH-specific rules for the design of facilities.

For example:

- 10 NYCRR § 712-2.4 (general hospital construction);
- 10 NYCRR § 713-4.3, 713-4.4, 713-4.9 and 713-4.10 (nursing home construction);
- 10 NYCRR § 714.4 (adult day health care program);
- 10 NYCRR § 715-2.4 (ambulatory medical facilities);
- 10 NYCRR § 717.2 (hospice);
- 14 NYCRR §§ 599.5 and 599.12 (OMH clinic construction); and
- 14 NYCRR §§ 814.2, 814.3, 814.6 and 814.7 (OASAS facility construction).

PPSs are likely to be interested in pursuing waivers of regulations that require facilities to submit a separate application when seeking a waiver of design requirements.

Pursuant to their authority under PHL § 2807(20)(e) and (21)(e), DOH, OMH and OASAS will entertain requests for waivers of these sections to the extent patient safety concerns are not implicated and the waivers are consistent with federal rules.

5. Pre-Opening Surveys

PPSs are likely to be interested in pursuing waivers that allow them to forego or expedite pre-opening surveys, which are required after completion of a construction project pursuant to 10 NYCRR § 710.9.

DOH will entertain requests for waivers of 10 NYCRR 710.9 on a case by case basis, and will grant them to the extent it does not implicate patient safety. However, certification surveys that are required of new providers applying for federal designation of facilities such as ambulatory surgery centers, rural health clinics and end stage renal disease facilities are separate from pre-opening surveys and cannot be waived.

D. PRIOR APPROVAL REVIEW

1. Prior Approval Review Process

OMH and OASAS require agency approval prior to allowing changes to health care facilities. OMH regulations subject projects and construction related to mental health programs to Prior Approval Review (PAR). Projects must undergo a comprehensive review if they meet one of several criteria, including if capital costs are $600,000 or greater.

Other projects undergo an E-Z PAR review whenever there is an establishment of a new satellite program or a significant increase in a facility’s caseload, among other circumstances. Similarly, OASAS subjects projects in substance use disorder facilities to two different levels of review.

PPSs are likely to be interested in pursuing waivers related to the PAR process in order to facilitate implementation of DSRIP project plans.

To afford additional flexibility as necessary to promote efficient implementation of DSRIP projects, OMH and OASAS will entertain requests for waivers of PAR regulations pursuant to its authority under PHL § 2807(20)(e) and (21)(e). For example, OMH would consider granting waivers to sections of 14 NYCRR Part 551 (pertaining to prior approval review for quality and appropriateness) and OASAS would consider granting waivers to sections of 14 NYCRR Part 810 (pertaining to establishment, incorporation and certification of providers of chemical dependence services).

2. Pre-Opening Surveys

PPSs are likely to be interested in pursuing waivers that allow them to forego or expedite pre-opening surveys, which are required after construction.

Pursuant to its authority under PHL § 2807(20)(e) and (21)(e), OMH and OASAS will entertain requests for waivers of these sections as appropriate, except in the case of MHL bonded properties. In addition, OMH and OASAS will consider self-certification for pre-opening surveys and will provide a streamlined review of design changes in conjunction with DSRIP projects.

E. OPERATING STANDARDS

1. Admission, Discharge and Transfer

PPSs are likely to be interested in pursuing waivers of regulations pertaining to admission, discharge and transfer in order to ease the transitioning of patients between care levels. For example:

- 10 NYCRR §§ 400.9 (transfer and affiliation agreements), 400.11 and 700.3 (assessment of long term care patients), 405.9 (admission and discharge) and 415.38 (long term ventilator dependent residents);
- 18 NYCRR § 505.20 (alternate care);
- 14 NYCRR § 36.4 (community placement of patients discharged or conditional release) and 14 NYCRR § 504.5 (community placement after behavioral health discharge); and
- 14 NYCRR Part 815.7 (discharge from OASAS services).

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 or state statutory requirements.

a. Transfer and Affiliation Agreements

PPSs are likely to be interested in pursuing waivers of 10 NYCRR § 400.9, which governs transfer and affiliation agreements.

Pursuant to its authority under PHL § 2807(20)(e) and (21)(e), DOH will entertain requests for waivers of such regulations on a case-by-case basis, to the extent such

waivers are necessary to facilitate implementation of DSRIP project plans.

b. Assessment of Long Term Care Patients

PPSs are likely to be interested in pursuing waivers of 10 NYCRR §§ 400.11 and 700.3, which govern assessment of long term care patients.

DOH could waive these regulations without the authority of PHL § 2807(20)(e) and (21)(e), as the regulations themselves authorize DOH to waive the requirements thereof for demonstration projects. DOH will entertain requests for such waivers in connection with DSRIP project plans, but only to the extent consistent with federal requirements including the Preadmission Screening and Resident Review (PASRR) process, and contingent upon demonstration of policies and procedures that will ensure appropriate assessment and placement post discharge.

c. General Hospital Discharges

10 NYCRR § 405.9(f)(7) requires hospitals to "ensure that no person presented for medical care shall be removed, transferred or discharged from a hospital based upon source of payment."

PPSs are likely to be interested in pursuing waivers of this regulation on grounds that the "source of payment" reference could be interpreted as applying to DSRIP funding, and thus could prevent hospitals within a PPS from transferring patients as contemplated under the PPS's DSRIP project plan.

Pursuant to its authority under PHL § 2807(20)(e) and (21)(e), DOH will entertain requests for waivers of 10 NYCRR § 405.9(f)(7) to avoid this result.

d. Alternate Care

18 NYCRR § 505.20 provides that no Medicaid reimbursement is available if a patient's initial admission was not both medically necessary and appropriate but was made because an appropriate placement at a lower level of care was not available at the time of admission.

PPSs are likely to be interested in pursuing waivers of this regulation in cases where an individual is ready to be transitioned from a general hospital or nursing home but there is no placement immediately available in order to allow the facility to continue to receive reimbursement until the individual is appropriately discharged.

The regulation reflects federal Medicaid requirements and cannot be waived pursuant to PHL § 2807(20)(e) and (21)(e).

e. 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. DOH already affords some flexibility as provided for in guidance distributed in April 2013 regarding the use of distinct physical space.

To provide additional flexibility, DOH will entertain requests for waivers of any applicable regulation on a case-by-case basis, to the extent such waivers are not inconsistent with federal requirements.

f. Practitioner Credentialing

Several regulations require practitioners to be credentialed, such as:

- 10 NYCRR §§ 405.2 and 405.4 (credentialing in hospitals);
- 10 NYCRR §§ 94 and 707 (credentialing for physician assistants); and
- 14 NYCRR 853 (credentialing for OASAS practitioners).

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 in order to facilitate DSRIP projects.

2. Home Visits

a. Article 28

10 NYCRR § 401.2(b) provides that an operator may use an operating certificate only for the designed site of operation (except where the Commissioner authorizes temporary operation at an alternate site due to an emergency).

PPSs are likely to be interested in pursuing a waiver for 10 NYCRR § 401.2(b) to allow practitioner home visits for all outpatient departments of general hospitals and D&TCs, which currently is permitted for FQHCs.

Pursuant to its authority under PHL § 2807(20)(e) and (21)(e), DOH will entertain requests for a waiver of § 401.2(b) to allow individuals with chronic illnesses to be visited at home. However, to permit Medicaid reimbursement for such services, DOH would need to 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 (SPA). This cannot be accomplished through a waiver; however, DOH is considering new regulations and a SPA amendment to achieve this.

b. Article 31 Home Visits

Currently, OMH providers can bill on a fee-for-service basis for offsite crisis visits. PPSs are likely to be interested in pursuing waivers so that they can also provide home visits on a non-emergency basis.

Pursuant to its authority under PHL § 2807(20)(e) and (21)(e), OMH will entertain requests for a waiver to allow individuals with mental illnesses to be visited at home. However, to permit Medicaid reimbursement for such services, OMH and DOH would need to amend regulatory provisions. This cannot be accomplished through a waiver; however, DOH is considering new regulations to achieve this. Additionally, OMH would need to submit a SPA

amendment to CMS. OMH is considering new regulations to achieve this.

c. Article 32 Home Visits

14 NYCRR Parts 822 (general service standards for chemical dependence outpatient and opioid treatment programs) and 841 (Medicaid reimbursement for chemical dependence services) pertain to billing for off-site services. PPSs are likely to be interested in pursuing regulatory waivers in order to facilitate their ability to provide home visits and to receive Medicaid reimbursement therefor.

No regulatory waiver is available due to federal requirements, but OASAS is submitting a SPA to move OASAS services to the rehabilitation option of the State Medicaid Plan, which would allow federal participation for off-site services.

3. Telemedicine/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 Therefore, no waivers are available pursuant to PHL § 2807(20)(e) and (21)(e).

OMH is in the process of issuing proposed regulations that would permit the use of telepsychiatry in Article 31 clinics, and is developing associated clinical and technical standards as well as billing procedures.

OASAS is working with DOH to develop the ability for OASAS programs to use telemedicine in its Article 32 clinics.

F. INFORMATION SHARING

PPSs are likely to be interested in pursuing regulatory waivers that would assist PPS providers in providing services to patients for purposes of diagnostic, treatment and care management at multiple points throughout the PPS without having to obtain separate consent forms for a patient at each point. For example:

- 10 NYCRR § 415.3(d)(1) (nursing home residents have the right to “personal privacy and confidentiality of his or her personal and clinical records which shall reflect… the resident’s right to approve or refuse the release of personal and clinical records to any individual outside the facility except when: (a) the resident is transferred to another health care institution; or (b) record release is required by law;”) and

- 10 NYCRR § 751.9(n) (diagnostic and treatment center patients have the right to “approve or refuse the release or disclosure of the contents of his/her medical record to any health-care practitioner and/or health-care facility except as required by law or third-party payment contract”);

- 10 NYCRR §§ 763.2(a)(10) and 766.1(a)(11) (home care patients have the right to “privacy, including confidential treatment of patient records, and refusal of their release to any individual outside the agency except in the case of the patient’s transfer to a health care facility, or as required by law or third party payment contract”); and

- 10 NYCRR § 794.1(a)(10) (hospice patients have the right to “confidential treatment of patient/family records, and may approve or refuse their release to any individual outside the hospice except in the case of the patient’s transfer to a health care facility, or as required by law or third-party payment contract”).

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. For example, federal regulations require patient consent for disclosure of substance use disorder information from certain providers, and OASAS has no ability to waive this requirement. See 42 C.F.R. § 2.31. State law also imposes confidentiality requirements upon protected health information in general as well as HIV and mental health information. Pursuant to MHL § 33.13, OMH providers can only exchange information with other treatment providers without consent for treatment purposes if those providers are licensed or funded by OMH, or if there is an agreement with OMH to do so.

Because patient consent issues are governed by HIPAA and state confidentiality statutes, there is no ability to waive regulations under PHL § 2807(20)(e) and (21)(e). However, 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.

G. WORKFORCE FLEXIBILITY

1. Home Care Orders by NPs and PAs

PPSs are likely to be interested in pursuing regulatory changes to allow physician assistants (PAs) to issue orders related to the provision of home health care in LHCSAs. At the same time, they are likely to be interested in pursuing regulatory changes that would broaden home care ordering authority to NPs and PAs to issue and sign orders for home care in CHHAs.

Current state regulation for LHCSAs allows nurse practitioners (NPs) to issue and sign orders for home health care. State regulations for LHCSAs could be amended to also allow physician assistants to sign orders as well. The proposed change to state regulation would take 9-12 months. PAs could be allowed to sign medical orders for home care as the function of PAs is similar to the function of NPs. DOH may pursue regulatory changes to allow PAs to sign orders for LHCSAs.

However, federal regulations do not allow NPs or PAs to sign medical orders for CHHAs and LTHHCPs. So it would not be possible to allow NPs or PAs to sign medical orders for home care services in CHHAs and LTHHCPs. No waiver is available pursuant to its authority under PHL § 2807(20)(e) and (21)(e).

2. Nurse-Driven Protocols

Under current law, a physician or certified 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.

DOH cannot authorize nurse-driven protocols pursuant to its authority under PHL § 2807(20)(e) and (21)(e), as statutory changes would be needed. DOH will consider developing a legislative proposal to achieve this.

3. Advanced Home Health Aides

PPSs are likely to be interested in pursuing waivers to authorize certain home health aides to administer medications.

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. The workgroup's guidance will assist DOH in developing recommendations for a future legislative proposal.

4. Emergency Medical Services

a. Community Paramedicine

At present, PHL Article 30 provides that only 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.

As indicated, this would not be permissible under PHL Article 30, and because it is statutory in nature it cannot be waived under PHL § 2807(20)(e) and (21)(e). However, DOH will consider recommending legislative changes.

b. Emergency Transport

PPSs are likely to be interested in pursuing regulatory waivers to enable EMS providers to transport of 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, within the confines of the ambulance service's operating certificate, and in fact this is a common practice. Accordingly, no regulatory waiver relief is necessary.

H. OTHER

As previously noted, this document is intended to provide guidance to PPSs to help them prepare to submit DSRIP Project Plan applications. This guidance should be viewed as a starting point and, as PPS plans become more concrete and it appears that there are additional areas where waivers may be appropriate, the agencies will refine this document accordingly.