

December 1, 2016

Bronx-Lebanon Hospital Center P.P.S. Sam Shutman, VP Managed Care & Business Development Bronx-Lebanon Hospital Center 1276 Fulton Avenue Bronx, New York 10456

Dear Mr. Shutman:

The Department of Health (Department), the Office of Mental Health (OMH), the Office of Alcoholism and Substance Abuse Services (OASAS) are pleased to respond to the request for waivers from certain regulatory requirements submitted under the Delivery System Reform Incentive Payment (DSRIP) Program. This letter responds to the request submitted by Bronx-Lebanon Hospital Center in its capacity as lead for the Bronx-Lebanon Hospital Center Performing Provider System.

Pursuant to Public Health Law (PHL) 2807(20)(e) and (21)(e) and in connection with DSRIP Project Plans and projects under the Capital Restructuring Financing Program which are associated with DSRIP projects, the Department, OMH, and OASAS may waive regulations for the purpose of allowing 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. Further, any waivers approved under this authority may not exceed the life of the project or such shorter time periods as the authorizing commissioner may determine.

Accordingly, any regulatory waivers approved herein are for projects and activities as described in the Project Plan application and any implementation activities reasonably associated therewith. Such regulatory waivers may no longer apply should there be any changes in the nature of a project. It is the responsibility of the PPS and the providers that have received waivers to notify the relevant agency when they become aware of any material change in the specified project that goes beyond the scope for which the waiver was granted. Further, any regulatory waivers approved are only for the duration of the projects for which they were requested.

The approval of regulatory waivers is contingent upon the satisfaction of certain conditions. In all cases, providers must be in good standing with the relevant agency or agencies. Other conditions may be applicable as set forth in greater detail below. The failure to satisfy any such conditions may result in the withdrawal of the approval, meaning that the providers will be required to maintain compliance with the regulatory requirements at issue and could be subject to enforcement absent such compliance.

Specific requests for regulatory waivers are addressed below.

1 BLHC 10 NYCRR 400.11(a) 2.a.iii, 2.b.iv

Background and Justification submitted with your request:

This project involves the transition and coordination of care which will implicate PRIs under the regulation. BLHC PPS requests a waiver of 10 NYCRR 400.11(a), which restricts staff who do not satisfy the credentials set forth in the regulations from completing a PRI necessary for initial or continued placement in a nursing home. This restriction would limit the flexibility required of project teams in implementing design plans and facilitating the transfer of residents from hospitals to nursing homes. The PPS anticipates that the PRI's will be performed by professionals with more extensive credentials than those identified in the regulations. These professionals should be permitted to conduct such assessments prior to the residents' initial or continued placement in long-term care facilities. Therefore, by waiving this regulation the PPS would be allowed the flexibility of assessing potential residents in a careful and strategic manner that enhances the goals of the PPS and the patient.

Response to Waiver Request:

PRI Requirement. Approvable on a case-by-case basis. 10 NYCRR 400.11(a) requires Hospital/Community PRI or PRI to be completed by a registered professional nurse who has successfully completed a training program in patient case mix assessment approved by the department to train individuals in the completion of the patient review form. The Department requires more information on the type of providers and credentials of the professionals the PPS proposes to utilize for conducting assessments prior to resident's initial or continued placement in long term care facilities. Please send an email to jahnhoy.smith@health.ny.gov with further detail.

2	BLHC	10 NYCRR 710.7	2.a.i, 2.a.iii, 2.b.i, 2.b.iv, 3.a.i, 3.c.i, 3.d.ii,
3.f.i, 4.a.iii, 4.c.ii			

Background and Justification submitted with your request:

This project involves expanding the networks capacity to provide timely access to care by adapting and restructuring the facilities in the most economic fashion through integration and collaboration. BLHC PPS requests a waiver of 10 NYCRR 710.7 which requires an applicant to receive Department written approval that submission requirements are complete and that construction may be commenced. The PPS is concerned that this additional review process will unduly delay commencing construction for new facilities and space required by DSRIP projects delaying the ability to provide access to care. The PPS requests that expedited review for such construction be permitted in order to facilitate project implementation with the DSRIP timeframe allowing the PPS a chance to fulfill DSRIP goals.

Response to Waiver Request:

Approval to Start Construction. **Approvable on a case-by-case basis.** 10 NYCRR 710.7(a) states that the applicant may seek approval to start construction of the project, or one or more phases thereof, upon the filing with the Department of the completed contract documents consistent with all previous approvals. The Department will review such requests on a case-by-case basis and will expedite the review of all DSRIP projects.

3 BLHC 14 NYCRR 810 3.a.i

Background and Justification submitted with your request:

This project involves expanding the networks capacity to provide timely access to care by adapting and restructuring the facilities in the most economic fashion through integration and collaboration. BLHC PPS requests a waiver of 14 NYCRR 810 to limit the regulatory application and review process associated with the delivery of OASAS-related services. BLHC PPS is concerned that this review process may delay project implementation and undermine the achievement of DSRIP milestones. BLHC PPS will need, in some circumstances, the ability to modify primary care facilities to allow for the incorporation of mental health services and vice versa.

Response to Waiver Request:

Clarification Needed. OASAS requests clarification on the request as SUD is not referenced. As previously stated OASAS will waive review for need and financial feasibility requirements, but will not waive certification requirements. The Agency will provide an expedited review process for DSRIP projects. Please send requested clarification to Trishia Allen of OASAS at <u>Trishia.Allen@OASAS.NY.gov</u>.

 4
 BLHC
 10 NYCRR 600.9(c)
 2.a.i, 2.a.iii, 2.b.i, 2.b.iv, 3.a.i, 3.c.i,

 3.d.ii, 3.f.i, 4.a.iii, 4.c.ii,
 2.a.i, 2.a.iii, 2.b.iv, 3.a.i, 3.c.i,

Background and Justification submitted with your request:

This project will involve the participation of non-established providers in order to effectuate the goals of the project and DSRIP by mitigating provider gaps. BLHC PPS requests a waiver of 10 NYCRR 600.9 which prohibits sharing of gross revenues or net profits unless the other entity has received establishment approval. This regulation could be interpreted as prohibiting the distribution of funds to non-established providers who are part of the same PPS. Without the waiver, this regulation could serve as an obstacle to the flow of DSRIP funds within BLHC PPS, which is a key element of the DSRIP program.

Response to Waiver Request:

Revenue Sharing. **Approved**. The PPS requested a waiver of 10 NYCRR § 600.9(c), pertaining to revenue sharing. The waiver is approved to the extent that the regulation otherwise would prohibit providers from receiving DSRIP incentive payments distributed by the PPS Lead.

5 BLHC 10 NYCRR Part 83 2.a.i, 3.a.i

Background and Justification submitted with your request:

This project involves integrated delivery systems which will involve co-location of care to provide seamless co-located services throughout the PPS patient population. BLHC PPS requests a waiver of 10 NYCRR Part 83, including 83.2 (a) (definition of shared health facilities), 83.4 and 83.5. This waiver is sought in order to remove or limit impediments to service co-location under the DSRIP projects. The relief of Part 83 will allow the co-location of medical providers and behavioral and substance abuse treatment providers in the same settings fostering DSRIP's goal of integrated delivery systems. Such co-location will allow for seamless and coordinated behavioral health, substance abuse treatment, medical care, and palliative care for patients. Furthermore, the Department will also oversee and provide diligent high-level review of the PPS project implementation plans before any patient activities commence. This

review will ensure that all activities are in accordance with patient safety standards and other state DSRIP goals.

Response to Waiver Request:

Shared Space/Co-location: No Waiver Needed. Please see attached guidance relative to allowable initiatives relative to "Shared Space/Co-Location". No waiver is needed to the extent providers follow the attached guidance. The Department/OMH/OASAS do not have the authority to issue any regulatory waivers beyond what is allowable by federal regulations and policy.

6 BLHC 14 NYCRR 85.4 2.a.i, 3.a.i

Background and Justification submitted with your request:

This project involves integrated delivery systems which will involve co-location of care to provide seamless co-located services throughout the PPS patient population. BLHC PPS requests a waiver of 10 NYCRR Part 83, including 83.2 (a) (definition of shared health facilities), 83.4 and 83.5. This waiver is sought in order to remove or limit impediments to service co-location under the DSRIP projects. The relief of Part 83 will allow the co-location of medical providers and behavioral and substance abuse treatment providers in the same settings fostering DSRIP's goal of integrated delivery systems. Such co-location will allow for seamless and coordinated behavioral health, substance abuse treatment, medical care, and palliative care for patients. Furthermore, the Department will also oversee and provide diligent high-level review of the PPS project implementation plans before any patient activities commence. This review will ensure that all activities are in accordance with patient safety standards and other state DSRIP goals.

Response to Waiver Request:

Shared Space/Co-location. No Waiver Needed. Please see attached guidance relative to allowable initiatives relative to "Shared Space/Co-Location". No waiver is needed to the extent providers follow the attached guidance. The Department/OMH/OASAS do not have the authority to issue any regulatory waivers beyond what is allowable by federal regulations and policy.

7 BLHC 14 NYCRR 587

2.b.iv, 3.a.i, 3.c.i

Background and Justification submitted with your request:

This project involves the integration of primary care setting, behavioral health and FQHC services to create an integrated system that coordinates care for patients with complex conditions to improve health and reduce hospitalization. This integration will require flexibility in staffing across these organizations. BLHC PPS requests a waiver of 14 NYCRR 587 which prohibits outpatient programs without an operating certificate and imposes restrictions on changes to physical space, location, use of additional sites and change in capacity. The waiver would remove or limit any obstacles for establishing new programs through the coordination of two existing already-licensed providers. The DSRIP initiatives require integrated care models which require joint programs among licensed providers under PHL Article 28 and Mental Hygiene Law ("MHL") Articles 31 and/or 32. These requirements should be waived to permit joint programs among licensed providers to allow for new programs to open through the

coordination of two or more existing licensed providers. Additionally, as the DSRIP projects are implemented the PPS will require a certain level of flexibility in adapting projects to ensure that there are adequate resources to serve patient populations. For example, BLHC PPS will need flexible staffing requirements to allow for adaptation for multiple sites.

Response to Waiver Request:

PAR/CON/Program Standard Exemption Requests. (Department/OMH/OASAS Joint Response) Denied. In response to regulatory waiver requests of any of the State agencies (The Department, OMH and/or OASAS) to eliminate either the processes by which a program is licensed/certified (e.g., Certificate of Need, Prior Approval Review, etc.) or licensure/certification altogether, none of the State agencies are currently in the position to waive such requirements. While State agencies may waive certain regulatory requirements for DSRIP projects to avoid duplication of requirements and to promote the efficient implementation of projects, regulations related to patient safety cannot be waived. Regulations pertaining to State facility oversight, including OMH Prior Approval Review (PAR), Department Certificate of Need (CON) and OASAS Certification applications, and standards for the certification and operations of programs establish minimally gualifying criteria to promote public safety. However, as had been indicated in previous regulatory waiver requests, the agencies will consider waiving the components of the licensure/certification processes relative to assessment of need and financial feasibility – limiting the licensure/certification reviews to current regulatory compliance and physical plant/environmental standards. The State agencies will expedite the review of all DSRIP-related CON/PAR applications to the extent possible.

8 BLHC 14 NYCRR 588.5 2.b.iv, 3.a.i, 3.c.i,

Background and Justification submitted with your request:

This project involves the integration of primary care setting, behavioral health and FQHC services to create an integrated system that coordinates care for patients with complex conditions to improve health and reduce hospitalization. This integration will require flexibility in staffing across these organizations. BLHC PPS requests a waiver of 14 NYCRR 588 to remove the requirement that an OMH operating certificate is required for a location whose expansion or operation is approved due to waivers pursuant to an approved DSRIP program. This regulation restricts the co-location of services that provide behavioral health services at a primary care site by requiring that providers comply with the substantive requirements of Parts 587 and 588 in order to receive reimbursement. This restriction would require providers to comply with the substantive requirements of 588. This waiver should be granted to allow BLHC PPS providers adequate reimbursement under the DSRIP program and to ensure that specific projects are financially stable. This will promote the expansion of integrated care models.

Response to Waiver Request:

PAR/CON/Program Standard Exemption Requests. (Department/OMH/OASAS Joint Response) Denied. In response to regulatory waiver requests of any of the State agencies (the Department, OMH and/or OASAS) to eliminate either the processes by which a program is licensed/certified (e.g., Certificate of Need, Prior Approval Review, etc.) or licensure/certification altogether, none of the State agencies are currently in the position to waive such requirements. While State agencies may waive certain regulatory requirements for DSRIP projects to avoid duplication of requirements and to promote the efficient implementation of projects, regulations related to patient safety cannot be waived. Regulations pertaining to State facility oversight, including OMH Prior Approval Review (PAR), Department Certificate of Need (CON) and OASAS Certification applications, and standards for the certification and operations of programs establish minimally qualifying criteria to promote public safety. However, as had been indicated in previous regulatory waiver requests, the agencies will consider waiving the components of the licensure/certification processes relative to assessment of need and financial feasibility – limiting the licensure/certification reviews to current regulatory compliance and physical plant/environmental standards. The State agencies will expedite the review of all DSRIP-related CON/PAR applications to the extent possible.

9 BLHC 14 NYCRR 814.7 2.a.i, 3.a.i

Background and Justification submitted with your request:

This project involves integrated delivery systems which will involve co-location of care to provide seamless co-located services throughout the PPS patient population. BLHC PPS requests a waiver in order to facilitate integrated services across the PPS. BLHC PPS seeks flexibility for partner organizations who locate services in shared space with OASAS providers. The regulations outline specific physical requirements for the space provided and this waiver would allow the PPS to adhere to one of the main DSRIP goals of integrating primary care, mental health services, and substance abuse treatment services. In order to promote such collaboration and integration, OASAS providers need to have flexibility to collaborate with other provides in established space and in the provision of patient services.

Response to Waiver Request:

Denied. OASAS 814.7 requires providers entering into a shared space arrangement develop and implement a plan for the protection of patient confidentiality consistent with federal confidentiality requirements. As such this requirement cannot be waived.

10 BLHC 10 NYCRR Part 703 2.b.iv, 3.a.i, 3.c.i

Background and Justification submitted with your request:

This project involves the integration of primary care setting, behavioral health and FQHC services to create an integrated system that coordinates care for patients with complex conditions to improve health and reduce hospitalization. This integration will require flexibility in staffing across these organizations. BLHC PPS seeks a waiver of 10 NYCRR Part 703 in order to co-locate services and integrate care. Under these regulations, Article 31 or Article 32 providers must meet all of the requirements of Department regulations (such as CON, licensure and related regulations applicable to Article 28 sites). A waiver would facilitate the integration of care under the DSRIP projects by permitting Article 31 and 32 licensed facilities to add primary care without being required to fulfill burdensome regulatory requirements under two sets of regulations. In order to co-locate services and integrate care across the PPS to meet the requirement of all DSRIP projects, Article 31 and 32 licensed facilities will need to add primary care. To do so within the given timeframe of DSRIP, these facilities should not be required to independently meet Article 28 requirements.

Response to Waiver Request:

Shared Space/Co-location. No Waiver Needed. Please see attached guidance relative to allowable initiatives relative to "Shared Space/Co-Location". No waiver is needed to the extent providers follow the attached guidance. The Department/OMH/OASAS do not have the authority to issue any regulatory waivers beyond what is allowable by federal regulations and policy.

11 BLHC 10 NYCRR 86-4.9 2.a.i, 2.aii, 2.b.iv, 3.a.i, 3.c.i

Background and Justification submitted with your request:

This project involves the expansion of capacity to provide timely access to care by integrating the network in the most economic fashion. This project involves the co-location and integration of services and it is understood that patients should have access to multiple types of providers on the same day. This serves the DSRIP goal of integrated behavioral health and primary care providers in achieving better outcomes for patients.

Response to Waiver Request:

Shared Space/Co-location. No Waiver Needed. Please see attached guidance relative to allowable initiatives relative to "Shared Space/Co-Location". No waiver is needed to the extent providers follow the attached guidance. The Department/OMH/OASAS do not have the authority to issue any regulatory waivers beyond what is allowable by federal regulations and policy.

12 BLHC 10 NYCRR 86-4.9(i) 2.a.i, 2.a.iii, 2.b.i, 2.b.iv, 3.a.i, 3.c.i,

3.d.ii, 3.f.i, 4.a.iii, 4.c.ii

Background and Justification submitted with your request:

This project involves the integration of care models. In order to be successful the project needs the ability to provide multiple services to patients in in flexible settings to enhance DSRIP goals of integration and increased access to care. This project will involve at-risk patients facing medical conditions, transportation and mobility issues that may limit their access to care. By allowing flexible care models, services can be provided in the most beneficial setting needed for a particular patient. BLHC PPS requests this waiver that prohibits FQHC services to be provided to patients whose status is expected to permanently preclude return to the FQHC and for the provision of off-site services. BLHC PPS projects will require clinical sites to have the ability to serve patients who may not have the capacity to receive care onsite, due to circumstances such as lack of transportation or illness. Without a waiver, the regulations will act as an obstacle to the BLHC PPS's ability to provide at-risk populations with high-quality care and increased access. FQHCs and providers require flexibility to offer a wide range of services to patients who may not return on-site.

Response to Waiver Request:

Approved.

13 BLHC 10 NYCRR 86-8 2.b.i, 3.a.i

Background and Justification submitted with your request:

In order to provide integrated care models and care coordination, providers would be needed to provide multiple services to patients to in flexible settings to enhance DSRIP goals of integration and increased access to care. This project will involve at-risk patients facing transportation and mobility issues that may limit their access to care. By allowing flexible care models, services can be provided in the most beneficial setting needed for a particular patient.

BLHC PPS requests a waiver of 10 NYCRR 86-8. This regulation sets limitations on discounting, packaging, combining and other reductions or denials of payment for multiple procedures and/or medical services provided to patients on the same date of service. This restriction will greatly impact the PPS' financial sustainability. For example, project 2.b.i serves adults with at least two comorbid chronic conditions and children with complex medical conditions that require co-management by multiple subspecialists and primary care providers. project 3.a.i involves the integration of behavioral health with primary care in order to serve patients with chronic mental and comorbid medical illnesses. These projects require the utilization of multi-disciplinary care plans to treat each patients multiple medical and/or behavioral conditions during a single visit. For example, project 2.b.i serves adults with at least two comorbid chronic conditions and children with complex medical conditions that require comanagement by multiple subspecialists and primary care providers. This waiver is requested in order to ensure that claims for multiple services provided to a patient on the same day are reimbursable in full. Full reimbursement will allow these projects to receive adequate funding and become financially sustainable. This waiver will also aide the PPS in meeting a foundational goal of the DSRIP project – to reduce hospitalization visits by 25%- by treating chronic mental and comorbid medical illnesses in one session. By choosing to treat taking the comorbid medical illnesses (i.e. diabetes, asthma), you risk the chronic mental health disorder becoming symptomatic prior to the next scheduled visit, and vice versa. This will create predictable situations of the patient requiring immediate medical care, in an emergency room, or even worst scenarios for the patient (incarceration, attempted and/or success suicidal actions).

Response to Waiver Request:

Denied. APG packaging, consolidation, and discounting has been addressed within the context of integrated services providers certified under 10 NYCRR Part 404. For approved integrated services providers, the 10 percent APG discount for multiple behavioral health services provided on a single day has been eliminated. Additionally, Medicaid has eliminated the multiple Evaluation and Management (E&M) consolidation logic so that when two E&Ms are billed (e.g., one for physical health and a second for behavioral health), the APG grouper/pricer no longer packages the second E&M into the APG payment. Medicaid will pay integrated service providers \$75 for the second E&M.

14 BLHC 10 NYCRR 670.1 (a-c) 3.d.ii, 3.f.i, 4.a.iii, 4.c.ii

2.a.i, 2.a.iii, 2.b.i, 2.b.iv, 3.a.i, 3.c.i,

Background and Justification submitted with your request:

This project involves expanding the PPS' capacity to provide timely access to care by adapting and restructuring the facilities in the most economic fashion through integration and collaboration. Co-location and integration of services is an integral part of the DSRIP projects and it is anticipated that patients will receive services on the same day. BLHC PPS requests a waiver of 10 NYCRR 670.1 (a-c) in order to allow for flexibility in expanding services needed to attain the DSRIP project milestones. BLHC PPS requires the ability to promptly reconfigure care systems in order to integrate and align service delivery across the network. DSRIP

projects require the expansion of services to fulfill community needs. Requiring new CON applications and a public need assessment could delay DSRIP project implementation. BLHC PPS requests the Department to consider conferring approval for projects concurrently with or as part of the DSRIP project application review in assure that the PPS has sufficient time to implement projects and reach DSRIP milestones.

Response to Waiver Request:

Public Need and Financial Feasibility. Approved. The PPS requested waivers of 10 NYCRR 670.1, with respect to the public need and financial feasibility components of the CON process. Waivers are approved, however, that:

- No waiver is available for establishment applications.
- Only the public need and financial feasibility component of the CON process is waived, meaning that a construction application still needs to be filed through NYSE-CON and provider compliance will still be reviewed.

15 BLHC 10 NYCRR Part 710 2.a.i, 2.a.iii, 2.b.i, 3.a.i

Background and Justification submitted with your request:

This project involves integrated delivery systems which require the use of improved HIT technologies. These technologies are necessary to allow for interoperability and improved data sharing across the PPS to enhance the provision of care. BLHC PPS requests a waiver of 10 NYCRR Part 710, specifically 710.1 and 710.2, particularly in order to limit the review process applied to the integration of mental health services into an established site that is currently providing medical or health services. BLHC PPS requests that this limited review replace other agency review processes in order to limit the administrative burden that multiple review processes would have on DSRIP project implementation. The listed projects require the expansion of HIT technologies and interoperability. This will include capital investments in new EHR technologies to improve data sharing across the PPS. A wavier of these regulations would allow BLHC PPS to not submit new CON applications for prior review and approval for all DSRIP activities. Without a waiver, the PPS could face delays in implementing such necessary changes and prove an obstacle to the PPS meeting DSRIP project milestones.

Response to Waiver Request:

HIT Standards: Approved. The PPS requested waivers pertaining to CON review of Health Information Technology (HIT) changes in existing medical facilities. The waiver request is approved to waive the financial review, however, the Department must review each project on a case-by- case basis to ensure IT standards are met. The PPS should contact the Department's Office of Health Information Technology (OHIT) for approval. To do so, please contact: <u>SHIN-NY@health.ny.gov</u>.

16 BLHC 10 NYCRR Part 405 3.d.ii, 3.f.i, 4.a.iii, 3.c.ii

2.a.i, 2.a.iii, 2.b.i, 2.b.iv, 3.a.i, 3.c.i,

Background and Justification submitted with your request:

This project will involve the utilization of licensed professionals to deliver care to patient populations. As the projects move to a more integrated delivery system, providers will require flexibility in the credentialing process to be able to seamlessly provide services at multiple sites.

Otherwise, provider participation may be deterred and this could affect the PPS' ability to engage necessary providers for the projects. BLHC PPS seeks a waiver of 10 NYCRR Part 405, specifically 405.2(e)(3) and 405.4(c)(5), in order to restructure the credentialing process within the PPS. BLHC PPS would like to have uniform standards addressing things such as exclusion screenings for Medicare and Medicaid and primary source verification. These commons processes will also assure consistent standards are promoted throughout the PPS ensuring patient safety. A flexible and integrated credentialing process would allow benefit a coordinate care model in implementing DSRIP programs. This waiver would also reduce the administrative burdens and fees on each of the PPS partner organization. By allowing a uniform credentialing process, health care professionals would have more flexibility in practicing in different settings as needed for care coordination without the delay of unnecessary duplicative credentialing.

Response to Waiver Request:

Credentialing. Approved. The PPS requested waivers of 10 NYCRR 405.2, specifically 405.2(e)(3) and 405.4(c)(5), for the purpose of allowing the PPS to gather and store credentialing information in a central repository and share such information with PPS providers as appropriate is approved. There must be a process in place for each provider in the PPS. Each individual practitioner must be privileged by each facility.

17 BLHC 10 NYCRR Part 401 2.a.i, 2.b.iv, 3.a.i, 3.c.i, 3.f.i

Background and Justification submitted with your request:

This project involves significant restructuring to allow for the integration of delivery systems in order to provide care coordination by adding additional services across provider types. BLHC PPS requests this waiver of 10 NYCRR Part 401, specifically 401.2 (b), 401.3(d) and 401.3(e), in order to allow behavioral and/or substance abuse providers to operate primary care under the oversight of their regulatory agency in place of the Department and its attendant facility standards. BLHC PPS also seeks it to allow Article 28 providers to operate primary care at additional locations within space of a different provider who is separately licensed by a state agency. This waiver will enable the PPS to promote rapid system integration and provide the PPS with the flexibility to reconfigure the system as necessary. BLHC PPS also requests this waiver because of its anticipated integration of delivery systems under project 2.a.i. BLHC PPS anticipates that integrating the delivery system will require a significant restructuring of facilities including conducting a formal analysis of excess beds to determine provider capacity. BLHC PPS will be required to implement such changes rapidly to ensure that care is delivered quickly and efficiently. The approval process for downsizing Article 28 construction should be limited to an administrative review, provided no new services are being added, in order to allow this shift to occur quickly. The decertification of facilities process should be subject only to a limited review, regardless of scope or expense, to provide the PPS with the necessary flexibility. The regulations may be interpreted to prevent Article 28 providers from sharing space with any provider not licensed under Article 28, including a physician group practice, a clinic licensed by OMH, or a substance abuse clinic licensed by OASAS. This limitation would prohibit mental healthcare or substance abuse providers from providing care in Article 28 facilities, limiting the integration of care under the DSRIP projects.

Response to Waiver Request:

Shared Space/Co-location. No Waiver Needed. Please see attached guidance relative to allowable initiatives relative to "Shared Space/Co-Location". No waiver is needed to the

extent providers follow the attached guidance. The Department/OMH/OASAS do not have the authority to issue any regulatory waivers beyond what is allowable by federal regulations and policy.

18 BLHC 10 NYCRR Part 766 3.f.i, 4.a.iii, 4.c.ii 10 NYCRR Part 766

2.a.i, 2.a.iii, 2.b.i, 3.a.i, 3.c.i, 3.d.ii,

Background and Justification submitted with your request:

This project involves significant restructuring to allow for the integration of delivery systems in order to provide care coordination by adding alternate levels of care through at-home models. This will allow access to care for at-risk patient populations that are frail, have complex medical conditions or have mobility/transportation issues. BLHC PPS requests this waiver of 10 NYCRR Part 766, specifically 766.4(a), (b) and 766.5(a), (b), in order to allow for flexibility in ordering home care. BLHC PPS will work to keep hospital admissions down and the DSRIP projects seek to do this by providing care in alternate settings, including patients' homes. This waiver would permit physician assistants and nurse practitioners to order home care as necessary to support project initiatives of reducing inpatient admissions.

Response to Waiver Request:

Ordering of home care by Physician Assistants. Approved. The request to waive 10 NYCRR 766.4(b) is approved for the purpose of a physician assistant or nurse practitioner ordering home care services for patients as part of a DSRIP project. This waiver does not allow physicians assistants or nurse practitioners to provide home care services in the home unless they contract with a licensed home care service agency as detailed in 10 NYCRR 766.4(a) and as allowable under Federal and State law.

 19
 BLHC
 10 NYCRR Part 600
 2.a.i, 2.a.iii, 2.b.i, 2.b.iv, 3.a.i, 3.c.i,

 3.d.ii, 3.f.i, 4.a.iii, 4.c.ii
 2.a.i, 2.a.iii, 2.b.iv, 3.a.i, 3.c.i,

Background and Justification submitted with your request:

This project involves the integration of care models. In order to be successful the project needs the ability to provide multiple services to patients in in flexible settings to enhance DSRIP goals of integration and increased access to care. This project will involve at-risk patients facing medical conditions, transportation and mobility issues that may limit their access to care. By allowing flexible care models, services can be provided in the most beneficial setting needed for a particular patient. BLHC PPS requests a waiver of 10 NYCRR Part 600, specifically 600.2, in order to facilitate the integration of co-located services for DSRIP project implementation. This waiver would permit BLHC PPS to avoid demonstrating financial feasibility of a project in order to obtain a CON. This process would be burdensome, costly, and time consuming and creates automatic barriers that will interfere with the BLHC PPS' ability to succeed in providing immediate and comprehensive care for patients and in meeting the milestones and mandates of DSRIP. Additionally, a significant number of the DSRIP projects' financial feasibility will be assessed on achieving DSRIP milestones as well as the overall DSRIP outcomes statewide. Another main focus of the DSRIP program is to stimulate the integration of primary care, behavioral health and/or substance abuse treatment services. This goal will be more efficiently attained by the co-location of behavioral health, primary care, and other needed clinical services. This will permit the care-management team of a single patient to ensure that the patient is adhering to suggested care plans and has access to any additional services as

necessary. Integration would be most efficiently accomplished through a single provider with single licensing agency at certain sites of service, by integrating behavioral and/or substance abuse providers to operate primary care (OMH, OASAS or OPWDD). By removing the additional agency approval for these projects, BLHC PPS will have more flexibility to adapt in an efficient manner with a fully comprehensive provider system, within the DSRIP timeframe.

Response to Waiver Request:

Public Need and Financial Feasibility. Approved. The PPS requested waivers with respect to the public need and financial feasibility components of the CON process. Waivers are approved, however:

- No waiver is available for establishment applications.
- Only the public need and financial feasibility component of the CON process is waived, meaning that a construction application still needs to be filed through NYSE-CON and provider compliance will still be reviewed.

Integrated Services. Approved solely with respect to 14 NYCRR 599.4(r) and (ab), which will be waived contingent upon following the DSRIP Project 3.a.i Licensure Threshold Model outlined in Appendix A to this letter. However, the Department, OMH and OASAS do not believe any additional waivers are needed if providers are integrating services under such model. As noted in Attachment A, the use of this model is contingent upon, among other things:

- submission of an application by the PPS with the identification all providers involved in such model;
- the verification of the good standing of such providers by the Department, OMH and OASAS, as appropriate;
- satisfaction of the physical plant standards as delineated in Attachment A.

If a PPS later identifies the need for a waiver, a request can be made at that time.

20 BLHC 14 NYCRR Part 551 2.b.iv, 2.a.i, 3.a.i, 3.c.i

Background and Justification submitted with your request:

This project involves the integration of care models. In order to be successful the project needs the ability to provide multiple services to patients in in flexible settings to enhance DSRIP goals of integration and increased access to care. This project will involve at-risk patients facing medical conditions, transportation and mobility issues that may limit their access to care. By allowing flexible care models, services can be provided in the most beneficial setting needed for a particular patient. BLHC PPS requests a waiver of 14 NYCRR Part 551, specifically 551.6 and 551.7, in order to facilitate a streamlined approval process for the expansion of integrated care models to primary care sites as an automatic component of particular DSRIP projects. These waivers are requested to permit BLHC PPS to modify primary care facilities in order to integrate mental health and substance abuse services and vice versa. The requested waivers apply to regulations that require Article 31 providers which are licensed under OMH to undergo prior approval review if they undertake certain projects, including the establishment of a new satellite location and the expansion of caseload by twenty five percent (25%) or more for clinic treatment programs. Section 551.7 requires a demonstration of public need as part of this review. Furthermore, OASAS regulations require Article 32 licensed providers to undergo prior approval review if the provider offers services at a new location or increases capacity of a service where capacity is identified in the provider's operating certificate. Section 810.7 requires the applicant

to demonstrate public need for its project as part of the review. This additional approval review would be duplicative of the DSRIP process itself, since the PPS will already have to submit its implementation plan to the Department for review. A separate prior approval review process on top of the review process embedded into DSRIP program would be burdensome and could unduly delay implementation.

Response to Waiver Request:

PAR/CON/Program Standard Exemption Requests. (Department/OMH/OASAS Joint Response) Denied. In response to regulatory waiver requests of any of the State agencies (the Department, OMH and/or OASAS) to eliminate either the processes by which a program is licensed/certified (e.g., Certificate of Need, Prior Approval Review, etc.) or licensure/certification altogether, none of the State agencies are currently in the position to waive such requirements. While State agencies may waive certain regulatory requirements for DSRIP projects to avoid duplication of requirements and to promote the efficient implementation of projects, regulations related to patient safety cannot be waived. Regulations pertaining to State facility oversight, including OMH Prior Approval Review (PAR), Department Certificate of Need (CON) and OASAS Certification applications, and standards for the certification and operations of programs establish minimally qualifying criteria to promote public safety. However, as had been indicated in previous regulatory waiver requests, the agencies will consider waiving the components of the licensure/certification processes relative to assessment of need and financial feasibility - limiting the licensure/certification reviews to current regulatory compliance and physical plant/environmental standards. The State agencies will expedite the review of all DSRIP-related CON/PAR applications to the extent possible.

21 BLHC 14 NYCRR Part 810 2.b.iv, 2.a.i, 3.a.i, 3.c.i,

Background and Justification submitted with your request:

This project involves the integration of care models. In order to be successful the project needs the ability to provide multiple services to patients in in flexible settings to enhance DSRIP goals of integration and increased access to care. This project will involve at-risk patients facing medical conditions, transportation and mobility issues that may limit their access to care. By allowing flexible care models, services can be provided in the most beneficial setting needed for a particular patient. BLHC PPS requests a waiver of 14 NYCRR Part 810, specifically 810.6 and 810.7, in order to facilitate a streamlined approval process for the expansion of integrated care models to primary care sites as an automatic component of particular DSRIP projects. These waivers are requested to permit BLHC PPS to modify primary care facilities in order to integrate mental health and substance abuse services and vice versa. The requested waivers apply to regulations that require Article 31 providers which are licensed under OMH to undergo prior approval review if they undertake certain projects, including the establishment of a new satellite location and the expansion of caseload by twenty five percent (25%) or more for clinic treatment programs. Section 551.7 requires a demonstration of public need as part of this review. Furthermore, OASAS regulations require Article 32 licensed providers to undergo prior approval review if the provider offers services at a new location or increases capacity of a service where capacity is identified in the provider's operating certificate. Section 810.7 requires the applicant to demonstrate public need for its project as part of the review. This additional approval review would be duplicative of the DSRIP process itself, since the PPS will already have to submit its implementation plan to the Department for review. A separate prior approval review process on top of the review process embedded into DSRIP program would be burdensome and unduly could delay implementation.

Response to Waiver Request:

PAR/CON/Program Standard Exemption Requests. (Department/OMH/OASAS Joint Response) Denied. In response to regulatory waiver requests of any of the State agencies (the Department, OMH and/or OASAS) to eliminate either the processes by which a program is licensed/certified (e.g., Certificate of Need, Prior Approval Review, etc.) or licensure/certification altogether, none of the State agencies are currently in the position to waive such requirements. While State agencies may waive certain regulatory requirements for DSRIP projects to avoid duplication of requirements and to promote the efficient implementation of projects, regulations related to patient safety cannot be waived. Regulations pertaining to State facility oversight, including OMH Prior Approval Review (PAR), Department Certificate of Need (CON) and OASAS Certification applications, and standards for the certification and operations of programs establish minimally qualifying criteria to promote public safety. However, as had been indicated in previous regulatory waiver requests, the agencies will consider waiving the components of the licensure/certification processes relative to assessment of need and financial feasibility – limiting the licensure/certification reviews to current regulatory compliance and physical plant/environmental standards. The State agencies will expedite the review of all DSRIP-related CON/PAR applications to the extent possible.

22 BLHC 10 NYCRR Part 670 2.

2.a.i, 2.a.ii, 2.b.i, 2.b.iv, 3.a.i, 3.c.i

Background and Justification submitted with your request:

This project involves expanding the PPS's capacity to provide timely access to care by adapting and restructuring facilities in the most economic fashion through integration and collaboration. Co-location and integration of services is an integral part of the DSRIP projects and it is anticipated that this will require the investment and expansion of in primary care through the development of new primary care sites BLHC PPS requests a waiver of 10 NYCRR Part 670, specifically 670.1, 670.2 and 670.3, because DSRIP project implementation will require providers to undertake construction and service changes. These changes will implicate CON regulations. The Department is required to review and approve all DSRIP projects and their Implementation Plans to ensure that a community needs assessment has been conducted and that such projects were selected based on community need. Therefore, waiving these regulations would remove the burden and delay on the PPS regarding demonstration of public need and a separate application for projects. The expansion of new facilities may also involve the investment in HIT technology to allow for better integration across the PPS. The DSRIP projects will require construction and renovation for new sites and the expansion of space at Article 28 providers to create new spaces for integrated healthcare models. This waiver would provide the PPS with flexibility in expanding an integrated care model through the interoperability through investments in HIT technologies and EHR. This expansion would permit for improved communication across the PPS and the improvement of efficient integrated care delivery systems. Without this waiver, the PPS and all partners would be required to submit CON applications and be subject to prior review and approval. The physical modifications described above and HIT acquisition, installation, modification or outlay of capital should be encouraged. Without the waiver, BLHC PPS could be delayed and be unable to reach DSRIP project milestones.

Response to Waiver Request:

Public Need and Financial Feasibility: Approved. The PPS requested a waiver of 670.1, 670.2 and 670.3 with respect to the public need and financial feasibility components of the CON process. A waiver is approved, however, that:

- No waiver is available for establishment applications.
- Only the public need and financial feasibility component of the CON process is waived, meaning that a construction application still needs to be filed through NYSE-CON and provider compliance will still be reviewed.

The Department has agreed to temporarily permit providers that have been awarded Capital Restructuring Financing Program (CRFP) grant funds for projects that are exclusively Health Information Technology (HIT) projects without any physical construction or alteration of clinical space that normally would require a Certificate of Need (CON) or limited review application prior review and approval to submit a Construction Notice for the project in lieu of the application. HIT projects that do include construction are still subject to CON application prior review and approval for the entire project, inclusive of the HIT costs. Instructions for submitting a Notice for CRFP-funded HIT only projects can be found on the Department's website at <u>http://www.health.ny.gov/facilities/cons/nysecon/.</u>

23 BLHC 10 NYCRR Part 709 3.d.ii, 3.f.i, 4.a.ii, 4.c.ii

2.a.i, 2.a.iii, 2.b.i, 2.b.iv, 3.a.i, 3.c.i,

Background and Justification submitted with your request:

This project involves expanding the PPS' capacity to provide timely access to care by adapting and restructuring facilities in the most economic fashion through integration and collaboration. Co-location and integration of services is an integral part of the DSRIP projects and it is anticipated that this will require the investment and expansion of in primary care through the development of new primary care sites. This project requires the investment and expansion of in primary care through the development of new primary care sites. BLHC PPS requests a waiver of 10 NYCRR Part 709, specifically 709, 709.1, 709.2 and 709.3, because DSRIP project implementation will require providers to undertake construction and service changes. These changes will implicate CON regulations. The Department is required to review and approve all DSRIP projects and their Implementation Plans to ensure that a community needs assessment has been conducted and that such projects were selected based on community need. Therefore, waiving these regulations would remove the burden and delay on the PPS regarding demonstration of public need and a separate application for projects. The expansion of new facilities may also involve the investment in HIT technology to allow for better integration across the PPS. The DSRIP projects will require construction and renovation for new sites and the expansion of space at Article 28 providers to create new spaces for integrated healthcare models. This waiver will provide the PPS with flexibility in expanding an integrated care model through the interoperability through investments in HIT technologies and EHR. This expansion will permit improved communication across the PPS and the improvement of efficient integrated care delivery systems. Without this waiver, the PPS and its partners will be required to submit CON applications and be subject to prior review and approval. The physical modifications described above and HIT acquisition, installation, modification or outlay of capital should be encouraged. Without the waiver, BLHC PPS could be delayed and be unable to reach DSRIP project milestones.

Response to Waiver Request:

Public Need and Financial Feasibility. Approved. The PPS requested a waiver of 709 and, with respect to the public need and financial feasibility components of the CON process. A waiver is approved, however, that:

- No waiver is available for establishment applications.
- Only the public need and financial feasibility component of the CON process is waived, meaning that a construction application still needs to be filed through NYSE-CON and provider compliance will still be reviewed.

24BLHC10 NYCRR 86-4.9(c)(8)2.a.i, 2.a.iii, 2.b.i, 2.b.iv, 3.a.i, 3.c.i,3.d.ii, 3.f.i, 4.a.iii, 4.c.ii

Background and Justification submitted with your request:

This project involves the integration of care models. In order to be successful the project needs the ability to provide multiple services to patients in in flexible settings to enhance DSRIP goals of integration and increased access to care. This project will involve at-risk patients facing medical conditions, transportation and mobility issues that may limit their access to care. By allowing flexible care models, services can be provided in the most beneficial setting needed for a particular patient. This project permits facilities to provide care in alternative settings to help promote an integrated delivery systems. BLHC PPS requests a waiver in order to provide services off-site. The ability to provide services in alternate settings would allow for better integrated care delivery and increased access to services for patients. This waiver would permit BLHC PPS to serve patient populations in a setting that is most beneficial and conducive to treatment. For example, clinical treatment staff may require the flexibility of providing home visits to certain patients. Particular patient populations face mobility and transportation barriers making them unable to receive treatment on-site. These providers should be eligible to receive reimbursement for such services rendered for such visits since they serve to permit at-risk patients increased access to care. This increased flexibility will allow BLHC PPS to promote the integration of mental health services and reduce the reliance on emergency department and inpatient use. The DSRIP goal of increasing quality and access to care will be more efficiently achieved if the PPS is permitted flexibility in creating innovative delivery methods of treatment. The DSRIP projects listed would benefit from this waiver. BLHC PPS requests the Department to coordinate with the CMS and CHIP Services on a state plan amendment to move OASAS services to the rehabilitation option of the state plan. This change would allow Medicaid reimbursement for off-site providers to provide home visits. If OASAS is authorized, BLHC PPS requests OASAS to waiver relevant provisions of 14 NYCRR Parts 822 and 841 to authorize home visits for substance abuse treatment.

Response to Waiver Request:

Billing of off-site services. Denied. The Department of Health does not presently have CMS approval to pay Article 28 clinics for off-site services, other than for FQHCs.

25 BLHC 14 NYCRR 822-3.1(b) 3.d.ii, 3.f.i, 4.a.iii, 4.c.ii 2.a.i, 2.a.iii, 2.b.i, 2.b.iv, 3.a.i, 3.c.i,

Background and Justification submitted with your request:

This project involves the integration of care models. In order to be successful the project needs the ability to provide multiple services to patients in in flexible settings to enhance DSRIP goals of integration and increased access to care. This project will involve at-risk patients facing

medical conditions, transportation and mobility issues that may limit their access to care. By allowing flexible care models, services can be provided in the most beneficial setting needed for a particular patient. This project permits facilities to provide care in alternative settings to help promote an integrated delivery systems. BLHC PPS requests a waiver in order to provide services off-site. The ability to provide services in alternate settings would allow for better integrated care delivery and increased access to services for patients. This waiver would permit BLHC PPS to serve patient populations in a setting that is most beneficial and conducive to treatment. For example, clinical treatment staff may require the flexibility of providing home visits to certain patients. Particular patient populations face mobility and transportation barriers making them unable to receive treatment on-site. These providers should be eligible to receive reimbursement for such services rendered for such visits since they serve to permit at-risk patients increased access to care. This increased flexibility will allow BLHC PPS to promote the integration of mental health services and reduce the reliance on emergency department and inpatient use. The DSRIP goal of increasing quality and access to care will be more efficiently achieved if the PPS is permitted flexibility in creating innovative delivery methods of treatment. The DSRIP projects listed would benefit from this waiver. BLHC PPS requests the Department to coordinate with the CMS and CHIP Services on a state plan amendment to move OASAS services to the rehabilitation option of the state plan. This change would allow Medicaid reimbursement for off-site providers to provide home visits. If OASAS is authorized, BLHC PPS requests OASAS to waiver relevant provisions of 14 NYCRR Parts 822 and 841 to authorize home visits for substance abuse treatment.

Response to Waiver Request:

No Waiver Needed. The prohibition on Medicaid reimbursement for off-site OASAS clinic services is in Federal law, and therefore cannot be waived. However, with the recent approval of NYS's amended 1115 waiver, CMS will permit certain off-site clinic-associated services to be provided by licensed OASAS providers to enrollees of Medicaid Managed Care Plans. Specifically, as Medicaid managed care plans transition to include behavioral health services (effective October 1, 2015 in New York City and an anticipated date of July 1, 2016 for the rest of the State), plans will begin authorizing off-site clinical services at locations other than a clinic's main site or satellite locations. The State will release guidance on the provision of off-site services under Medicaid managed care in the near future, which will assist in the development and implementation of DSRIP projects. The PPSs would not need a regulatory waiver for such services to be provided once these services are fully-authorized under Behavioral Health Medicaid Managed Care. Further, OASAS is in the process of a State Plan Amendment to permit the provision of off-site services under Medicaid Fee-For-Service with an anticipated effective date of January 1, 2016. To the extent regulatory impediments still exist, OASAS is willing waive specific requests.

26 BLHC 14 NYCRR 599.14 3.d.ii, 3.f.i, 4.a.iii, 4.c.ii 2.a.i, 2.a.iii, 2.b.i, 2.b.iv, 3.a.i, 3.c.i,

Background and Justification submitted with your request:

This project involves the integration of care models. In order to be successful the project needs the ability to provide multiple services to patients in in flexible settings to enhance DSRIP goals of integration and increased access to care. This project will involve at-risk patients facing medical conditions, transportation and mobility issues that may limit their access to care. By allowing flexible care models, services can be provided in the most beneficial setting needed for a particular patient. This project permits facilities to provide care in alternative settings to help

promote an integrated delivery systems. BLHC PPS requests waivers in order to provide services off-site. The ability to provide services in alternate settings would allow for better integrated care delivery and increased access to services for patients. This waiver would permit BLHC PPS to serve patient populations in a setting that is most beneficial and conducive to treatment. For example, clinical treatment staff may require the flexibility of providing home visits to certain patients. Particular patient populations face mobility and transportation barriers making them unable to receive treatment on-site. These providers should be eligible to receive reimbursement for such services rendered for such visits since they serve to permit at-risk patients increased access to care. This increased flexibility will allow BLHC PPS to promote the integration of mental health services and reduce the reliance on emergency department and inpatient use. The DSRIP goal of increasing quality and access to care will be more efficiently achieved if the PPS is permitted flexibility in creating innovative delivery methods of treatment. The DSRIP projects listed would benefit from this waiver. BLHC PPS requests the Department to coordinate with the CMS and CHIP Services on a state plan amendment to move OASAS services to the rehabilitation option of the state plan. This change would allow Medicaid reimbursement for off-site providers to provide home visits. If OASAS is authorized, BLHC PPS requests OASAS to waiver relevant provisions of 14 NYCRR Parts 822 and 841 to authorize home visits for substance abuse treatment.

Response to Waiver Request:

Denied. The prohibition on Medicaid reimbursement for off-site OMH clinic services is in Federal law, and therefore cannot be waived. However, with the recent approval of NYS's amended 1115 waiver, CMS will permit certain off-site clinic-associated services to be provided by licensed OMH providers to enrollees of Medicaid Managed Care Plans. Specifically, as Medicaid managed care plans transition to include behavioral health services (effective October 1, 2015 in New York City and an anticipated date of July 1, 2016 for the rest of the State), plans will begin authorizing off-site clinical services at locations other than a clinic's main site or satellite locations. The State will release guidance on the provision of off-site services under Medicaid managed care in the near future, which will assist in the development and implementation of DSRIP projects. The PPSs would not need a regulatory waiver for such services to be provided once these services are fully-authorized under Behavioral Health Medicaid Managed Care.

27 BLHC 14 NYCRR Part 841 3.d.ii, 3.f.i, 4.a.iii, 3.c.iii 2.a.i, 2.a.iii, 2.b.i, 2.b.iv, 3.a.i, 3.c.i,

Background and Justification submitted with your request:

This project involves the integration of care models. In order to be successful the project needs the ability to provide multiple services to patients in in flexible settings to enhance DSRIP goals of integration and increased access to care. This project will involve at-risk patients facing medical conditions, transportation and mobility issues that may limit their access to care. By allowing flexible care models, services can be provided in the most beneficial setting needed for a particular patient. This project permits facilities to provide care in alternative settings to help promote an integrated delivery systems. BLHC PPS requests a waiver in order to provide services off-site. The ability to provide services in alternate settings would allow for better integrated care delivery and increased access to services for patients. This waiver would permit BLHC PPS to serve patient populations in a setting that is most beneficial and conducive to treatment. For example, clinical treatment staff may require the flexibility of providing home visits to certain patients. Particular patient populations face mobility and transportation barriers

making them unable to receive treatment on-site. These providers should be eligible to receive reimbursement for such services rendered for such visits since they serve to permit at-risk patients increased access to care. This increased flexibility will allow BLHC PPS to promote the integration of mental health services and reduce the reliance on emergency department and inpatient use. The DSRIP goal of increasing quality and access to care will be more efficiently achieved if the PPS is permitted flexibility in creating innovative delivery methods of treatment. The DSRIP projects listed would benefit from this waiver. BLHC PPS requests the Department to coordinate with the CMS and CHIP Services on a state plan amendment to move OASAS services to the rehabilitation option of the state plan. This change would allow Medicaid reimbursement for off-site providers to provide home visits. If OASAS is authorized, BLHC PPS requests OASAS to waiver relevant provisions of 14 NYCRR Parts 822 and 841 to authorize home visits for substance abuse treatment.

Response to Waiver Request:

No Waiver Needed. The prohibition on Medicaid reimbursement for off-site OASAS clinic services is in Federal law, and therefore cannot be waived. However, with the recent approval of NYS's amended 1115 waiver, CMS will permit certain off-site clinic-associated services to be provided by licensed OASAS providers to enrollees of Medicaid Managed Care Plans. Specifically, as Medicaid managed care plans transition to include behavioral health services (effective October 1, 2015 in New York City and an anticipated date of July 1, 2016 for the rest of the State), plans will begin authorizing off-site clinical services at locations other than a clinic's main site or satellite locations. The State will release guidance on the provision of off-site services under Medicaid managed care in the near future, which will assist in the development and implementation of DSRIP projects. The PPSs would not need a regulatory waiver for such services to be provided once these services are fully-authorized under Behavioral Health Medicaid Managed Care. Further OASAS is in the process of a State Plan Amendment to permit the provision of off-site services under Medicaid Fee-For-Service with an anticipated effective date of January 1, 2016. To the extent regulatory impediments still exist, OASAS is willing waive specific requests.

28 BLHC 10 NYCRR Part 711 3.d.ii, 3.f.i, 4.a.iii, 4.c.ii 2.a.i, 2.a.iii, 2.b.i, 2.b.iv, 3.a.i, 3.c.i,

Background and Justification submitted with your request:

This project involves expanding the PPS' capacity to provide timely access to care by adapting and restructuring the facilities in the most economic fashion through integration and collaboration. Co-location and integration of services is an integral part of the DSRIP projects and it is anticipated that patients will receive services on the same day. BLHC PPS requests this waiver for 10 NYCRR Part 711, specifically 702.3, 711.2, 712-2.4, 713-4.3, 713-4.5, 713-4.7, 715-2.2 and 715-2.4, needed flexibility in expanding programs requiring new construction and renovation. Because of the integration of primary care and behavioral health services, the design of these new spaces may conflict with specific regulatory requirements for clinics and hospitals. Requiring that the PPS to comply with all requirements as set forth in such regulatory sources as the Guidelines for the Design and Construction of Health Care Facilities would be unduly burdensome. For example, the standards for behavioral health integration requirements where not drafted with physical and behavioral health integration in mind. Existing facilities may also undertake upgrades to increase their provision of primary care services requiring space reconfiguration for primary care providers to provide behavioral healthcare services at those sites requiring substantial construction. Additionally, undergoing a preopening survey process

could lead to delays affecting the PPS' ability to achieve DSRIP milestones. This waiver should be granted to permit the PPS to adapt efficiently for the DSRIP projects.

Response to Waiver Request:

Construction Standards. Denied. The PPS requested a waiver of 711, which set forth construction standards. Due to patient safety concerns, these regulations cannot be waived. However, the Department will expedite the review of projects associated with DSRIP Project Plans to the extent possible.

29BLHC10 NYCRR Part 7132.a.i, 2.a.iii, 2.b.i, 2.b.iv, 3.a.i, 3.c.i,3.d.ii, 3.f.i, 4.a.iii, 4.c.ii

Background and Justification submitted with your request:

This project involves expanding the PPS' capacity to provide timely access to care by adapting and restructuring the facilities in the most economic fashion through integration and collaboration. Co-location and integration of services is an integral part of the DSRIP projects and it is anticipated that patients will receive services on the same day. BLHC PPS requests a waiver of 10 NYCRR Part 713, specifically 713-4.4, 713-4.8, 713-4.9 and 713-4.10, because the PPS requires flexibility in expanding programs requiring new construction and renovation. Because of the integration of primary care and behavioral health services, the design of these new spaces may conflict with specific regulatory requirements for clinics and hospitals. Requiring that the PPS to comply with all requirements as set forth in such regulatory sources as the Guidelines for the Design and Construction of Health Care Facilities would be unduly burdensome. For example, the standards for behavioral health integration requirements where not drafted with physical and behavioral health integration in mind. Existing facilities may also undertake upgrades to increase their provision of primary care services requiring space reconfiguration for primary care providers to provide behavioral healthcare services at those sites requiring substantial construction. Additionally, undergoing a preopening survey process could lead to delays affecting the PPS' ability to achieve DSRIP milestones. This waiver should be granted to permit the PPS to adapt efficiently for the DSRIP projects.

Response to Waiver Request:

Construction Standards. Denied. The PPS requested a waiver which set forth construction standards. Due to patient safety concerns, these regulations cannot be waived. However, the Department will expedite the review of projects associated with DSRIP Project Plans to the extent possible.

30BLHC10 NYCRR 405.19(g)2.a.i, 2.a.iii, 2.b.i, 2.b.iv, 3.a.i, 3.c.i,3.d.ii, 3.f.i, 4.a.iii, 4.c.ii

Background and Justification submitted with your request:

This project involves expanding the PPS' capacity to provide timely access to care by adapting and restructuring the facilities in the most economic fashion through integration and collaboration. Such integration involves the need for flexibility in structuring care in such a way as to serve community needs efficiently. BLHC PPS requests a waiver of 10 NYCRR 405.19(g) in order to have flexibility in locating observation units beds in an integrated care facility without requiring such observation unit beds to be located in a distinct physical space, provided such

space has already been approved by the Department for a licensed bed. We ask that observation beds be considered a type of "swing bed" giving the provider discretion in locating patients based on individual need. The regulations outline that specific physical space requirements for observation unit beds. Because of the integration of primary care and behavioral health services, the design of these new spaces may conflict with specific regulatory requirements. In order to advance integration, the PPS requires the ability to adapt its facilities and designation of beds to best serve patient needs. Furthermore, we believe the Department should provide flexibility to the provider in determining the number of observation beds which should not be limited to 5% of the hospital's certified bed capacity. The PPS requires flexibility in providing and designated such beds as community and patient needs arise, particularly if we are to meet the established goal of reducing avoidable inpatient admissions. Greater flexibility in the number and location of observation beds will greatly assist in reaching that goal. The PPS also requests that observation units be extended to 48 hours for those patients in need of extended stays.

Response to Waiver Request:

Observation Beds. No Waiver Needed. 10 NYCRR 405.32 allow for observation beds using the scatter bed approach, effective November, 4, 2015. 10 NYCRR 405.19(g) has been repealed.

In cases where waivers are approved, the agencies will send letters directed to the providers which otherwise would be responsible for complying with the regulatory provisions at issue. Providers further will be advised that agency staff who conduct surveillance activities will be notified that these regulatory waivers have been approved; however, they should maintain a copy of their waiver letters at any site subject to surveillance.

Please note that the Department will publish on its website a list of regulatory waivers that have been approved to assist PPSs in determining whether additional waivers may be appropriate for the activities within a PPS. Additional requests for waivers, as well as any questions regarding the foregoing, may be sent by email to <u>DSRIP@health.ny.gov</u> with Regulatory Waiver in the subject line.

Thank you for your cooperation with this initiative. We look forward to working with you to transform New York's delivery system.

Sincerely,

Howard Lucker M.D.

Howard A. Zucker, M.D., J.D. Commissioner of Health

In hi I Sude

Ann Marie T. Sullivan, M.D. Commissioner New York State Office of Mental Health

Arlene González-Sáňchez Commissioner New York State Office of Alcoholism and Substance Abuse Services