NEW YORK STATE OF OPPORTUNITY. | Department of Health | Office of Mental Health | Office of Alcoholism and Substance Abuse Services

March 10, 2015

Ms. Christina Jenkins, Sr. V.P.
New York City Health and Hospitals-led PPS
JACOBI MEDICAL CENTER
125 Worth Street, Suite 507
New York, New York 10013

Dear Ms. Jenkins:

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 Jacobi Medical Center in its capacity as lead for the New York City Health and Hospitals-led Performing Provider System under the Delivery System Reform Incentive Payment (DSRIP) Program.

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 of 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 are 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 included in the New York City Health and Hospitals-led PPS Project Plan application are addressed below.

52.01 HHC ALL 10 NYCRR § 405.9(f)(7)

Background and justification provided in your request:

Section 405.9(f)(7) requires hospitals to ensure that patients may not be discharged or transferred to another location based upon source of payment. This regulation could be interpreted to prohibit hospitals from transferring their patients to other providers within the same PPS, since the hospital would have a financial relationship with the other provider. For example, if one hospital in a PPS were to transfer a patient to the lead coalition provider because the lead coalition provider specializes in treating the patient's condition, this could be viewed as a transfer based on source of payment since the lead coalition provider distributes DSRIP funds to the transferring hospital.

Response to waiver request:

Admission, Transfer and Discharge. No waiver needed. The PPS requested waivers of 10 NYCRR § 405.9(f)(7), which provide important protections related to the admission, transfer or discharge of patients from in-patient settings, including prohibiting decisions about admission, transfer or discharge based on source of payment. No regulatory waiver is needed for purposes of permitting transfers and discharges of patients between PPS partners, provided that decisions to admit, transfer or discharge are clinically based and appropriate documentation is made thereof.

52.02 HHC ALL 10 NYCRR § 600.9(c)

Background and justification provided in your request:

Section 600.9(c) prohibits a medical facility from sharing gross income or net revenue with an individual or entity that has not received establishment approval. This could be interpreted as prohibiting a hospital that receives Department funds under DSRIP from distributing those funds to non-established providers who are in the same PPS. Such an interpretation would be contrary to one of the key elements of DSRIP: the distribution of funds by the lead coalition provider to other providers participating in the PPS.

Response to waiver request:

Revenue Sharing. Approved. The PPS requested a waiver of 10 NYCRR § 600.9, 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.

52.03 HHC 2.b.iv, 3.b.i, 3.d.ii, 3.g.i 10 NYCRR § 766.4(a), (b)

Background and justification provided in your request:

Section 766.4 allows doctors, midwives, and nurse practitioners to order licensed home care services, but it does not allow physician's assistants (PAs) to order such care. As part of their efforts to keep patients out of the hospital, the DSRIP projects listed above are likely to involve orders for home care. Patients often are in need of home care services back at home after staying in a hospital (2.b.iv) or receiving palliative care (3.g.i). Patients who receive cardiovascular care (3.b.i) also may need home care services. Likewise, on some occasions, patients with asthma symptoms may need home care to help manage their symptoms back at

home (3.d.ii). Allowing PAs to order home care as part of these projects would make it easier for these providers to order such care and thus could potentially play a role in reducing inpatient admissions.

Response to waiver request:

Determination pending.

52.04 HHC 2.a.i, 3.a.i 10 NYCRR §§ 401.2(b), 401.3(d)

Background and justification provided in your request:

Section 401.2(b) allows the operating certificate of an Article 28 provider to be used only by the Article 28 operator at the Article 28 provider's site of operation. The Department has interpreted this to mean that the operator must have exclusive site control and cannot share the site with another entity. Section 401.3(d) prohibits an Article 28 provider from leasing or subletting any portion of its facility unless the entity that leases the facility conforms to all of the requirements imposed on Article 28 providers. At the very least, these two provisions prohibit 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 would prohibit Article 28 providers from allowing other providers with expertise in mental healthcare or substance abuse services to provide care in their facilities, thereby limiting their options to integrate care under Project 3.a.i. These two provisions could also be interpreted to bar an Article 28 provider from sharing space with another Article 28 provider. This interpretation would prevent residential care facilities from sharing space with primary care clinics, a possible aspect of Project 2.a.i.

Response to waiver request:

Integrated services. Approved solely with respect to14 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. The Department, OMH and OASAS have determined that no additional waivers are needed if providers are integrating services under such model. As noted in Appendix A, the use of this model is contingent upon:

- 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 Appendix A.

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

52.05 HHC 2.a.i, 2.b.iii, 3.a.i, 3.b.i 10 NYCRR §§ 670.1, 670.2, 670.3, 709.1, 709.2, 709.3, 710.1

Background and justification provided in your request:

When medical facilities seek to undertake certain projects, the certificate-of-need (CON) regulations cited above require those facilities to submit applications to the Department, demonstrate a public need for their projects, and obtain Department prior approval. The projects listed above are likely to require providers to undertake construction and service changes that would implicate the CON rules. In particular: a) Project 2.a.i requires a large investment in primary care capacity and some providers will need to expand operations in order to meet that

enhanced capacity; this may include the addition of primary care sites at residential care facilities; b) Project 2.a.i also requires investment health information technology (HIT) infrastructure, and some HIT investments enacted by providers—a group of providers that includes residential healthcare facilities—will fall within the scope of CON regulation; c) Project 3.a.i will likely require construction and renovation at Article 28 providers to create new spaces for behavioral healthcare, and likewise some Article 28 providers may provide services at new sites; and d) Projects 2.b.iii and 3.b.i will likely require the creation of new spaces to handle the increased demand for urgent care and cardiovascular services under DSRIP. Requiring a demonstration of public need and a separate application for these projects is unnecessary. Department approval of the DSRIP projects and their implementation plans should be sufficient, particularly in light of the fact that the PPS has conducted a community needs assessment, and used the results of that assessment to inform its project selection. If the Department is unwilling to waive these regulations in full, the Department should at least provide a highly expedited review process to ensure that DSRIP projects are not delayed.

Response to waiver request:

HIT Standards. Approved. The PPS requested waivers of 10 NYCRR § 710.1(b), 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: SHIN-NY@health.ny.gov.

Public Need and Financial Feasibility. Approved. The PPS requested waivers of 10 NYCRR §§ 670.1, 709 and 710.2, 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 need to be filed through NYSE-CON and provider compliance will still be reviewed.
- No waiver is available for specialized services, CHHA service area expansions, and hospital and NH bed increases, which will be determined on a case-by-case basis.

Integrated services. Approved solely with respect to14 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. The Department, OMH and OASAS have determined that no additional waivers are needed if providers are integrating services under such model. As noted in Appendix A, the use of this model is contingent upon:

- 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 Appendix A.

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

52.06 HHC 2.a.i, 2.b.iii, 3.a.i, 3.b.i 10 NYCRR §§ 702.3, 710.9, 711.2, 712-2.4, 715-2.2, 715-2.4

Background and justification provided in your request:

Sections 702.3 and 711.2 set construction standards for medical facilities in general; Section 712-2.4 provides specific standards for hospitals; and Sections 715-2.2 and 715-2.4 set standards for freestanding ambulatory care facilities. In addition, Section 710.9 requires a pre-opening survey after the completion of a construction project. In order to fulfill the goals of Project 2.a.i to provide more primary care services to underserved areas, there will be an expansion of the capacity of primary care providers, which will likely require new construction and renovation. Hospitals with aging facilities may also undertake upgrades in order to increase their provision of primary care services. Likewise, Projects 2.b.iii and 3.b.i will require an investment in primary care infrastructure; some facilities may have to be renovated in order to provide more urgent care and diabetes services, and it is also possible that new sites may need to be constructed. In addition, Project 3.a.i will require space reconfiguration for primary care providers in order to provide behavioral healthcare services at those sites, and substantial construction is likely to occur at some facilities under these projects. The design of these new spaces under these projects may conflict with particular regulatory requirements for the design of clinics and hospitals. Such regulatory requirements incorporate provisions of the Guidelines for the Design and Construction of Health Care Facilities, which set out detailed rules for these facilities. Having to follow all of these requirements could be particularly problematic in the context of the behavioral health integration requirement given that these standards where not written with physical and behavioral health integration in mind. Moreover, having to undergo the preopening survey process could lead to delays in the opening of the new unit, and therefore at the very least an expedited survey process is necessary.

Response to waiver request:

Public Need and Financial Feasibility. Approved. The PPS requested waivers of 10 NYCRR §§ 670.1, 709 and 710.2, 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 need to be filed through NYSE-CON and provider compliance will still be reviewed.
- No waiver is available for specialized services, CHHA service area expansions, and hospital and NH bed increases, which will be determined on a case-by-case basis.

Pre-Opening Surveys. Denied. The PPS requested waivers of 10 NYCRR § 701.9, pertaining to CON pre-opening surveys. These requests are denied, as pre-opening surveys pertain to patient safety. However, the Department will expedite pre-opening surveys connected with DSRIP projects to the extent possible.

Integrated services. Approved solely with respect to14 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. The Department, OMH and OASAS have determined that no additional waivers are needed if providers are integrating services under such model. As noted in Appendix A, the use of this model is contingent upon:

- 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 Appendix A.

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

52.07 HHC 3.a.i 14 NYCRR §§ 599.3(b), 599.4(r), (ab); 14 NYCRR §§ 800.2(a)(6), (14), 810.3, 810.3(f), (l)

Background and justification provided in your request:

OMH regulations require Article 28 providers to obtain an OMH license if they provide more than 10,000 mental health visits annually, or if mental health visits comprise more than 30 percent of the provider's annual visits and the total number of visits is at least 2,000 annual visits (the OMH threshold). OASAS regulations require an Article 28 provider to obtain certification from OASAS if it provides any substance abuse services. Under 3.a.i, Article 28 providers will increase their provision of both mental health and substance abuse services so that patients can receive physical and behavioral health services in one setting. It is highly likely that some of the providers participating in 3.a.i will cross the OMH threshold, and all Article 28 providers that provide any substance abuse services would be required to obtain OASAS certification. Requiring OMH and/or OASAS licensure would conflict with the goals of Project 3.a.i., and the certification process would be an unnecessary administrative burden. Further, having to comply with multiple licenses would force Article 28 providers to comply with new rules that would have little benefit to patients. For example, Article 28 providers are already required to maintain medical records that meet the Department's standards; requiring their records to also meet OMH standards would not improve patient care. Forcing providers to comply will new and unnecessary administrative processes and rules will discourage providers from providing such integrated care.

Response to waiver request:

Integrated services. Approved solely with respect to14 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. The Department, OMH and OASAS have determined that no additional waivers are needed if providers are integrating services under such model. As noted in Appendix A, the use of this model is contingent upon:

- 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 Appendix A.

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

52.08 HHC 3.a.i 14 NYCRR §§ 599.5(c), 599.12(a)(6)

Background and justification provided in your request:

The regulations cited above allow mental health providers licensed by OMH (Article 31 providers) to share program space only if they have a written space sharing plan that has been approved by OMH. As part of the behavioral health integration project, providers licensed by OMH are likely to share space with providers of physical health services. The PPS's implementation plan will indicate which providers are planning to share space, and assuming

the Department approves that implementation plan, the Department will approve the space sharing plans. Providers should not have to obtain a separate approval from OMH.

Response to waiver request:

OMH approved based on licensure threshold model. Approved solely with respect to14 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. The Department, OMH and OASAS have determined that no additional waivers are needed if providers are integrating services under such model. As noted in Appendix A, the use of this model is contingent upon:

- 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 Appendix A.

If you do not believe that this model meets your needs, or if you later identify the need for a waiver, please send us a request at DSRIP@health.ny.gov.

52.09 HHC 2.a.i, 2.b.iv, 3.a.i, 3.b.i, 3.d.ii Department: 10 NYCRR §§ 86-4.9(c)(8), 401.2(b); OMH: 14 NYCRR § 599.14; OASAS: 14 NYCRR § 822-3.1(b)

Background and justification provided in your request:

Section 86-4.9(c)(8) prohibits freestanding ambulatory care facilities from billing for services provided off-site. Section 401.2(b) allows an Article 28 to use its operating certificate only for services at its designated site of operation, which has been interpreted as prohibiting providers from providing services off-site. Sections 599.14 and 822-3.1(b) impose similar rules on mental health and substance abuse providers, respectively. Providers would benefit from the ability to provide services off-site in carrying out DSRIP projects. This ability would be particularly beneficial to carryout Project 2.a.i: allowing facilities to provide care in alternative settings would help promote an integrated delivery system and would discourage facilities from providing care in silos. Similarly, as part of the care transition project, a patient who is treated by a professional in a hospital may benefit from seeing that same professional at home (2.b.iv). Projects 3.b.i and 3.d.ii aim to improve cardiovascular and asthma care, and facility-based practitioners may seek to provide services in the home as part of that enhanced care. Social workers employed by Article 28 providers may seek to provide behavioral health services within a patient's home (3.a.i). In short, providers seek the flexibility to provide needed care in the setting that is most conducive to treatment.

Response to waiver request:

Department-Off-Site Services or Home Visits. Approved. The PPS requested waivers of 10 NYCRR § 401.2(b) for the purpose of allowing practitioners affiliated with Article 28 providers to provide services outside of the certified service site. The request is approved, contingent upon notification by the PPS of the specific providers, practitioners and services. However, reimbursement for the provision of such services would not be available absent approval of a State Plan Amendment (SPA) to the State Medicaid Plan and associated state regulations, both of which are being pursued by the Department. In addition, the Department will explore, through Value-based Payment options, incorporating more flexibility for home visits, telemedicine and team visits.

OMH-Disapprove waiver of 14NYCRR 599.14. This is prohibited by federal regulations.

OASAS- Approved. Such approval is contingent upon notification by the PPS of the specific providers, practitioners and services. However, reimbursement for the provision of such services would not be available absent approval of a State Plan Amendment (SPA) to the State Medicaid Plan being pursued by OASAS. Please note community based services to individuals in managed care will be reimbursable in community based settings as part of the demonstration.

Integrated services. Approved solely with respect to14 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. The Department, OMH and OASAS have determined that no additional waivers are needed if providers are integrating services under such model. As noted in Appendix A, the use of this model is contingent upon:

- 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 Appendix A.

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

52.10 HHC 3.a.i OMH: 14 NYCRR §§ 551.6, 551.7: OASAS: 14 NYCRR §§ 810.6, 810.7

Background and justification provided in your request:

Section 551.6 requires Article 31 providers who are licensed by 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 25 percent or more for clinic treatment programs. Section 551.7 requires a demonstration of public need as part of this review. Similarly, Section 810.6 requires Article 32 providers who are licensed by OASAS 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, and Section 810.7 requires the applicant to demonstrate public need for its project as part of the review. Project 3.a.i is likely to fall within the reach of these regulations. As part of behavioral health integration, Article 31 and Article 32 providers are likely to provide services at new locations—more specifically, they may provide care within an Article 28 facility. While establishing a new satellite location is technically subject to E-Z PAR review, in practice this process is not easy for providers: they must obtain a letter of support from a local government unit to demonstrate there is a public need for the project, and the process can be lengthy. Requiring prior approval review for the behavioral health integration project would be duplicative of the DSRIP process itself, since the PPS will already have to submit its implementation plan to the state for review. There is no need to impose a separate prior approval review process on top of the review process embedded into DSRIP itself.

Response to waiver request:

Integrated services. Approved solely with respect to14 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. The Department, OMH and OASAS have determined that no additional waivers are needed if providers are integrating services under such model. As noted in Appendix A, the use of this model is contingent upon:

- 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 Appendix A.

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

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 of Health 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 DSRIP@health.ny.gov 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 Zucker M.D.

Howard A. Zucker, M.D., J.D.
Acting Commissioner
New York State Department of Health

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

Arlene González-Sánchez
Commissioner
New York State Office of Alcoholism
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