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

March 9, 2015

Westchester Medical Center
WESTCHESTER MED CTR
June Keenen, Senior VP, Delivery System Transformation
100 Woods Road
Valhalla, NY 10595

Dear Ms. Keenen,

The Department of Health (DOH), 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 Westchester Medical Center in its capacity as lead for the Westchester Medical Center, Inc. PPS 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, DOH, 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 Westchester Medical Center PPS Project Plan application are addressed below.

21.01 Westchester 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 visits annual (the OMH threshold). OASAS regulations require an Article 28 provider to obtain a 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 3.a.i. Going through 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 DOH 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. Patient safety: Waiving licensure requirements is not likely to endanger patient safety because Article 28 providers are already required to comply with a detailed regulatory regime aimed at ensuring patient safety. Nevertheless, working with OMH and OASAS, Article 28 providers that increase their provision of mental health and substance abuse services under 3.a.i will examine their policies to determine if any further policies need to be developed to ensure patient safety given the service changes. If any further policies are required, they will be modeled on OMH and OASAS regulatory requirements.

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. DOH, 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 DOH, 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.

21.02.01 Westchester 2.a.iv (SPLIT Request in 2 parts) 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. DOH 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 with all of the requirements imposed on Article 28 providers. In effect, 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. These provisions could also be interpreted more broadly and prohibit the sharing of space with any other provider, even if that provider does have an Article 28 license. These rules therefore conflict with the PPS's projects. Under Project 2.a.iv, the two hospitals that are creating medical villages are likely to share space with other providers, such as physician groups or Article 28 clinics. Under Project 3.a.i, some Article 28 providers are likely to share space with mental health or substance abuse clinics in order to capitalize on the expertise of those providers.

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. DOH, 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 DOH, 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.

21.02.02 Westchester 3.a.i (SPLIT Request in 2 parts)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. DOH 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 with all of the requirements imposed on Article 28 providers. In effect, 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. These provisions could also be interpreted more broadly and prohibit the sharing of space with any other provider, even if that provider does have an Article 28 license. These rules therefore conflict with the PPS's projects. Under Project 2.a.iv, the two hospitals that are creating medical villages are likely to share space with other providers, such as physician groups or Article 28 clinics. Under Project 3.a.i, some Article

28 providers are likely to share space with mental health or substance abuse clinics in order to capitalize on the expertise of those providers.

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. DOH, 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 DOH, 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.

21.03 Westchester 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 will develop a detailed implementation plan and timeline in DY1 that will indicate which providers are planning to share space, and assuming DOH approves that plan, DOH will approve the space sharing plans. Providers should not have to obtain a separate approval from OMH.

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. DOH, 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 DOH, 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.

21.04 Westchester 2.a.i, 2.a.iv, 3.a.i, 3.c.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 DOH, demonstrate a public need for their projects in the application, and

obtain DOH prior approval before initiating their projects. 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; b) Project 2.a.i also requires investment health information technology infrastructure, and some HIT investments enacted by providers—a group of providers that will most likely include residential health care facilities upon final implementation —will fall within the scope of CON regulation; c) Project 2.a.iv involves the decertification of beds at two hospitals and their replacement with primary care, emergency department, and observation unit services; d) Project 3.a.i will likely require construction and renovation at Article 28 providers to create new spaces for behavioral health care, and likewise some Article 28 providers may provide services at new sites, and e) Project 3.c.i may require the creation of new spaces to handle increased demand for diabetes services. DOH 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. DOH should therefore waive the sections of the CON regulations that require a demonstration of need and financial review for the projects listed above (a limited architectural review of the projects under these regulations is still appropriate).

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 of 10 NYCRR §§ 670.1, 709 and 710.2 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.

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 DOH must review each project on a case by case basis to ensure IT standards are met. The PPS should contact DOH's Office of Health Information Technology (OHIT) for approval. To do so, please contact: SHIN-NY@health.ny.gov.

Bed Capacity. Approved. The PPS requested waivers of 10 NYCRR §§ 710 and 401(e), pertaining to the CON process for changes in bed capacity. These requests are approved, provided that submission of information through NYSE-CON is necessary for decreases in bed capacity and administrative review necessary for increases in bed capacity. DOH will expedite all DSRIP projects.

21.05 Westchester 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. DOH, 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 DOH, 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.

21.06 Westchester 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 DOH 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.

21.07 Westchester 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.

21.08 Westchester 2.a.i, 2.a.iii, 2.b.iv, 3.a.i, 3.a.ii, 3.c.i, 3.d.iii, 4.b.i, 4.b.ii DOH: 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 offsite. 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 multiple DSRIP projects. This ability would be particularly beneficial in carrying out 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. Under Project 2.b.iv, a visit from a patient's facility-based practitioner may be part of a strategy to reduce readmissions. Social workers employed by Article 28 providers may seek to provide behavioral health services within a patient's home under Project 3.a.i. Project 3.c.i aims to improve diabetes care, and facility-based practitioners may seek to provide services in the home as part of that enhanced care. In short, providers seek the flexibility to provide needed care in the setting that is most conducive to treatment.

Response to waiver request:
Additional information needed. OASAS requests additional information specifically identifying the services to be provided, identifying the provider and identifying where the services will be provided. Please provide such information to Trishia Allen of OASAS via email at Trishia.Allen@oasas.ny.gov. Further, OASAS is currently in the process of amending the State Plan Amendment to accommodate off-site services

21.09 Westchester 2.b.iv, 3.c.i 10 NYCRR § 400.11(a)

Background and justification provided in your request: This request is to waive 10 NYCRR §400.11(a), to permit staff who do not satisfy the credentials set forth in the regulations to conduct an assessment necessary for initial or continued placement in a nursing home to perform the assessments. The projects requested for are: 2.a.i.; 2.b.iv.; 2.b.vii.; 3.a.i.; and 3.a.ii., and may be supplemented as project teams work on implementation design plans, to facilitate the transfer of residents from hospitals to nursing homes by allowing health care professionals with a broader range of credentials than those identified in the regulations to conduct the assessment of potential residents prior to their initial or continued placement in long-term care facilities.

Response to waiver request:
PRI requirement. Approvable on a case-by-case basis. 10 NYCRR 400.11(a) requires Hospital/Community PRI or PRI as well as the SCREEN We will waive the PRI requirement in 400.11(a), as well as the credentials of the person required to complete it, on a case-by-case basis provided that the provider notify, and obtain approval from, the department for an alternative screening tool.

SCREEN requirement. Denied. We cannot waive the SCREEN portion of this regulation or the credentialing requirements for the person who completes the SCREEN as this is a federal requirement.

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
And Substance Abuse Services