March 10, 2015

Ben Wade, Assistant V.P.
Montefiore Hudson Valley Collaborative
MONTEFIORE MEDICAL CENTER
Planning Department
111 East 210th Street
Bronx, New York 10467

Dear Mr. Wade:

The Department of Health (Department), the Office of Mental Health (OMH), the Office of Alcoholism and Substance Abuse Services (OASAS) and the Office for People with Developmental Disabilities 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 Montefiore Medical Center in its capacity as lead for the Montefiore Hudson Valley Collaborative 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, OASAS and OPWDD 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 Montefiore Hudson Valley Collaborative PPS Project Plan application are addressed below.

19.01 Monte Introduction

Background and justification provided in your request:

The HVC has outlined the following areas of needed regulatory relief. As the HVC will engage in even more detailed planning in the coming months, we request the ability to refine and expand upon the items discussed herein and to engage in dialogue with state agencies about regulations that appear to be relevant based upon projects described in this application submission. Through these discussions, the HVC may wish to extend individual waiver requests to other projects not otherwise outlined.

Of note, many of these requests are made because state agencies have not yet articulated an expedited review process for DSRIP activities. If such processes are made available, the HVC may withdraw some of the waiver requests discussed below.

Response to waiver request:

Not applicable as a regulatory waiver not requested.

19.02 Monte 2.a.i.; 2.a.iv.; 2.b.iii.; 3.a.i. and 3.a.ii. Title 10, 83.2(a)

Background and justification provided in your request:

We seek a waiver of 10 NYCRR 83.2 (a), which defines shared health facilities, for projects 2.a.i.; 2.a.iv.; 2.b.iii.; 3.a.i. and 3.a.ii. We may supplement this request with additional information during the implementation phase; in particular we anticipate needing relief from the requirements set forth in Part 83, particularly sections 83.4 and 83.5.

We believe that there are no risks to patient safety in the waiving of this regulation. First, the HVC will seek to align with existing state patient safety provisions related to the services that will be co-located to the maximum extent possible. Further, DSRIP performance metrics ensure that all PPSs will be held accountable to the highest of patient safety standards in the execution of project activities. Finally, the Department will also have ample time to review HVC project implementation plans at a high level before any activities commence – we believe this review step will ensure that all planned activities are in accordance with patient safety and other state DSRIP goals. In this application, we seek relief from 83.2 (a) to permit co-location of medical providers and behavioral and substance use treatment providers in the same settings. Given the explicit aim of DSRIP to foster integrated delivery systems that seamlessly coordinate behavioral health, substance use treatment, medical care, and palliative care for patients, we believe it is key to remove or limit impediments to service co-location.

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.

19.03 Monte 2.a.i.; 2.a.iii.; 2.a.iv.; 2.b.iii.; 3.a.i.; 3.a.ii.; 3.b.i.; 3.d.iii.; 4.b.i.; and 4.b.ii. Title 10, 86-4.9

Background and justification provided in your request:

We seek a waiver of 10 NYCRR, 86--4.9, which establishes that the basis of payment for most clinic services provided in hospital outpatient departments and diagnostic and treatment centers under Article 28 of the Public Health Law is the threshold visit. We seek this waiver for projects 2.a.i.; 2.a.iii.; 2.a.iv.; 2.b.iii.; 3.a.i.; 3.a.ii.; 3.b.i.; 3.d.iii.; 4.b.i.; and 4.b.ii. We also request an examination of the policies and procedures that prohibit Federally Qualified Health Centers from being reimbursed for more than a single service in a single day. We believe that the reimbursement policy that stems from this regulation and policy stance will significantly undermine efforts to deliver coordinated, comprehensive care to patients. As an example, many of the patients we serve may require a primary care oriented visit and a visit to address mental illness in the same day; the current billing architecture does not permit reimbursement beyond single threshold visit. We anticipate that many of the patients we serve face significant transportation and logistical barriers to accessing care. To the extent that the HVC in the execution of all project activities outlined above can promote streamlined access to services available in a single location on a single day, we believe patients with complex needs will benefit significantly and the DSRIP vision of integrated service delivery will be achieved. Put simply, we request an enabling reimbursement structure to support this vision.

Response to waiver request:

Reimbursement issue. Denied. This is a federal requirement which we do not have the authority to waive.

19.04 Monte 2.a.i.; 2.a.iv.; 2.b.iii.; 3.a.i., and 3.a.ii. Title 10, 401.2 (b)

Background and justification provided in your request:

We seek a waiver of 10 NYCRR 401.2 (b), which notes that an operating certificate shall be used only by the established operator at the designated site of operation. We seek this waiver for projects 2.a.i.; 2.a.iv.; 2.b.iii.; 3.a.i., and 3.a.ii.

Specifically, we seek this waiver to permit: (1) behavioral and/or substance use providers to operate primary care under the oversight of their regulatory agency in place of the Department and its attendant facility standards; (2) Article 28 providers to operate primary care at additional locations within space of a different provider who is separately licensed by a state agency and; (3) Article 28 staff to conduct reimbursable home visits in a patient's home. For these activities, we would want approval from the Department to relocate services or add on additional locations beyond the designated site of operation with no further certificate of need activity; ideally this approval would be conferred concurrent with or as part of the DSRIP project application approval process. This waiver will enable the PPS to promote rapid system reconfiguration and service integration. As an example, authorizing patient homes as a site of service eligible for the provision of care and reimbursement will promote ease of access and

reduce reliance on ED and inpatient settings as sources of primary care or behavioral health services. The PPS will work with service providers and community based organizations to reduce barriers to access and this may necessitate patients being evaluated and treated in their residences.

Response to waiver request:

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. The Department will explore, through Value-based Payment options, incorporating more flexibility for home visits, telemedicine and team visits.

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.

19.05 Monte Title 10, 401.3

Background and justification provided in your request:

We seek a waiver of 401.3, which requires the submission of written changes to existing medical facilities to the Department of Health and approval prior to implementation. The projects we seek this waiver for include: 2.a.iv; 2.b.iii.; 3.a.i. and 3.a.ii. All of the projects above require either expanding capacity, modifying existing services, and/or relocating services. As an example, under project 2.a.iv, the HVC intends to optimize current regional inpatient delivery system by evolving excess hospital capacity (as determined through the community needs assessment activity and conversations with PPS partners) to serve other purposes such as respite behavioral health services, housing, and pharmacy services. Through this project, several of the hospital facilities the HVC is working with will transition excess capacity to make way for services identified as critical to HVC communities, namely urgent care, resuscitation services, and a rapid assessment zone to enable ED triage. As another example, under project 3.a.i, the HVC will cultivate three models: (1) the integration and co-location of behavioral health into primary care clinics; (2) integration and co-location of primary care into behavioral health clinics; and (3) the collaborative care model (telephonic behavioral health services) at sites where physical co-location is not possible. Pursuing these models will require the modification of physical facilities to meet service integration goals.

Response to waiver request:

Construction Standards. Denied. The PPS requested a waiver of §§ 401.3, which set forth construction standards. Due to patient safety concerns, this regulation cannot be waived. However, the Department will expedite the review of projects associated with DSRIP Project Plans to the extent possible.

19.06 Monte 2.a.i.; 2.a.iii; 2.a.iv; 2.b.iii.; 3.a.i.; 3.a.ii.; 3.b.i.; 3.d.iii.; 4.b.i.; and 4.b.ii. Title 10, Part 405; specifically 405.2(e)(3) and §405.4(c)(5)

Background and justification provided in your request:

We seek a waiver of 10 NYCRR Part 405; specifically 405.2(e)(3) and §405.4(c)(5) pertaining to projects 2.a.i.; 2.a.iii; 2.a.iv; 2.b.iii.; 3.a.i.; 3.a.ii.; 3.b.i.; 3.d.iii.; 4.b.i.; and 4.b.ii. in order to streamline the credentialing process within the PPS. This waiver will allow the HVC PPS to establish a shared credentialing process and standards to: (1) conduct primary source verification; (2) screen for Medicare and Medicaid exclusion; and (3) assure consistent standards to promote quality and patient safety, relying on data available to partner organizations and to the PPS through its own monitoring and data collection. The waiver would reduce the cost and administrative burden of credentialing by each partner organization, and would allow health care professionals to practice in different settings as needed for care coordination without duplicative credentialing. The waiver is also requested to permit certain practices that may be necessary to implement coordinated care models, such as allowing a physician in private practice to supervise more than two physicians' assistants (10 NYCRR 94.2).

Response to waiver request:

Credentialing. Approved. The PPS requested waivers of 10 NYCRR § 405.2, 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.

19.07 Monte 2.a.i.; 2.a.iii.; 2.a.iv.; 2.b.iii.; 3.a.i.; 3.a.ii.; 3.b.i.; 3.d.iii.; 4.b.i.; and 4.b.ii. Title 10, 405.1 (c)

Background and justification provided in your request:

We seek a waiver of 405.1 (c), which requires that any person, partnership, stockholder, corporation or other entity with the authority to operate a hospital to be approved for establishment by the Public Health Council. We seek this waiver for projects 2.a.i.; 2.a.iii.; 2.a.iv.; 2.b.iii.; 3.a.i.; 3.a.ii.; 3.b.i.; 3.d.iii.; 4.b.i.; and 4.b.ii. to exempt the PPS from the requirement of becoming an established operator as it carries out its role in governing the PPS, creating collaborative arrangements, and approving protocols that impact the delivery of services.

Response to waiver request:

Administrative Services. No waiver needed. The PPS requested waivers of 10 NYCRR §§ 600.9 and 405.1(c). No waiver is needed to the extent the PPS is performing administrative functions for purposes of administering PPS activities. However, if the PPS is performing functions described in 10 NYCRR § 405.1(c) and thus acts as the active parent of another entity, it will require establishment as set forth in § 405.1(c).

19.08 Monte 2.a.i and 2.b.iii to Title 10, 405.19 (g) (2,5(b))

Background and justification provided in your request:

We seek a waiver of 10 NYCRR 405.19 (g) (2,5 (b)) for projects 2.a.i and 2.b.iii to (1) add observation unit beds without prior review under section 10 NYCRR 710.1(c)(2) or (3), regardless of project cost; (2) to waive the applicable provisions of Parts 711 and 712-2 and section 712-2.4 of 10 NYCRR for construction projects approved or completed after January 1, 2011; and (3) to waive the physical space and location requirements applicable to placement of observation beds.

In order to reduce avoidable hospital admissions, readmissions, and ED visits; to facilitate the proper assessment and treatment of patients who may be able to be cared for in the community, or, in accordance with a care transitions program, returned to a community setting following a short stay in the hospital as an outpatient, providers will need to expand capacity of observation beds and to have flexibility in the location of the beds.

Response to waiver request:

Observation Beds. No waiver needed to increase the number of observation beds. The PPS requested waivers in connection with observation beds. No regulatory waiver is needed for a provider to increase its number of observation beds; however, the provider must follow construction standards if applicable.

Construction Standards. Denied. The PPS requested waivers of §§ 401.3 and 711 through 715, 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.

19.09 Monte 2.a.i, 3.a.ii Title 10, 405.9 (b)(2) and (f)(7)

Background and justification provided in your request:

We seek a waiver of 10 NYCRR 405.9 (b)(2) and (f)(7) for projects 2.a.i.; and 3.a.ii. to permit providers to implement PPS-approved protocols for care transitions and care pathways when making admission decisions and conducting discharge planning and placement of Medicaid and Uninsured patients.

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.

19.10 Monte 2.a.i.; 2.a.iii.; 2.a.iv.; 2.b.iii.; 3.a.i.; 3.a.ii.; 3.b.i.; 3.d.iii.; 4.b.i.; and 4.b.ii Title 10, 600.9

Background and justification provided in your request:

We seek a waiver of 600.9 for projects 2.a.i.; 2.a.iii.; 2.a.iv.; 2.b.iii.; 3.a.i.; 3.a.ii.; 3.b.i.; 3.d.iii.; 4.b.i.; and 4.b.ii. to exempt the PPS from the requirement of becoming an established operator as it carries out its role in governing the PPS, creating collaborative arrangements, and approving protocols that impact the delivery of services.

Response to waiver request:

Administrative Services. No waiver needed. The PPS requested waivers of 10 NYCRR §§ 600.9. No waiver is needed to the extent the PPS is performing administrative functions for purposes of administering PPS activities. However, if the PPS is performing functions described in 10 NYCRR § 405.1(c) and thus acts as the active parent of another entity, it will require establishment as set forth in § 405.1(c).

19.11 Monte 2.a.i.; 2.a.iii.; 2.a.iv.; 2.b.iii.; 3.a.i.; 3.a.ii.; 3.b.i.; 3.d.iii.; 4.b.i.; and 4.b.ii. Title 10, 600.9 (c)

Background and justification provided in your request:

We seek a waiver of 10 NYCRR 600.9 (c) for projects 2.a.i.; 2.a.iii.; 2.a.iv.; 2.b.iii.; 3.a.i.; 3.a.ii.; 3.b.i.; 3.d.iii.; 4.b.i.; and 4.b.ii to ensure that DSRIP-related distribution of revenue and collaborative arrangements among providers do not violate this regulation, which prohibits regulated entities from fee-splitting or sharing in gross revenues of non-established entities. This regulation has been identified as a potential impediment to DSRIP flow of funds. We seek a waiver to ensure that any financial components of agreements or other processes providing for the DSRIP flow of funds among PPS partners for the purpose of DSRIP project execution is permissible. It is important to distinguish this critical PPS function in a manner that it does not constitute illegal fee-splitting with non-established providers.

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.

19.12 Monte 2.a.iv.; 2.b.iii.; 3.a.i. and 3.a.ii. Title 10, 670.1 (a-c)

Background and justification provided in your request:

We seek a waiver of 10 NYCRR 670.1 (a-c) for projects 2.a.iv.; 2.b.iii.; 3.a.i. and 3.a.ii. to facilitate the addition or expansion of services and capacity to meet DSRIP goals.

Through this waiver, the HVC will promote rapid system reconfiguration, to better integrate and align service delivery across the continuum, and to situate services such as behavioral health treatment in alternative locations like primary care sites and elsewhere in the community, thereby reducing reliance on ED and inpatient hospital care. All of the projects listed above will require the expansion of capacity or adding or changing existing services.

For example, under project 3.a.i, the HVC will cultivate three models: (1) the integration and co-location of behavioral health into primary care clinics; (2) integration and co-location of primary care into behavioral health clinics; and (3) the collaborative care model (telephonic behavioral health services) at sites where physical co-location is not possible. Pursuing these models will require the modification of physical facilities to meet service integration goals.

Project 3.a.ii will involve increasing or adding crisis mobilization and stabilization services in the community.

We seek relief from having to file new certificates of need, go through determinations of public need, and achieve approval prior to implementation, as these steps will significantly delay project activities. We also submit for consideration the idea that the Department would confer approval for these project activities concurrent with or as a part of the DSRIP Project application approval process.

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.

19.13 Monte Determination of Public Need Title 10, 709.1

Background and justification provided in your request:

We seek a waiver of 709.1, which outlines a process for determining public need for health services and medical facilities as a part of applications for construction. The HVC seeks this waiver for project 2.a.iv, creating a medical village using existing hospital infrastructure, and 3.a.i, integration of primary care and behavioral health. Under project 2.a.iv, the HVC intends to optimize current regional inpatient delivery system by evolving excess hospital capacity (as determined through the community needs assessment activity and conversations with PPS partners) to serve other purposes such as respite behavioral health services, housing, and pharmacy services. Under project 3.a.i, the HVC will cultivate three models: (1) the integration and co-location of behavioral health into primary care clinics; (2) integration and co-location of primary care into behavioral health clinics; and (3) the collaborative care model (telephonic behavioral health services) at sites where physical co-location is not possible. To develop these three models, the HVC will need to undertake activities implicated under 709.1, such as construction to modify facilities to meet the objectives of projects 2.a.iv and 3.a.i. For example, under the auspices of 2.a.i, several of the hospital facilities the HVC is working with will transition excess capacity to make way for services identified as critical to HVC communities, namely urgent care, resuscitation services, and a rapid assessment zone to enable ED triage, all of which will require construction and modification of existing facilities. We request a waiver because the regulation, as currently constructed, could significantly delay the timeline for these activities and undermine the likelihood of meeting DSRIP project milestones. Further, we suggest that the comprehensive analysis and community health needs activities embedded in DSRIP fulfill many of the objectives of the determination for public need process.

Response to waiver request:

Public Need. Approved. The PPS requested waivers of 10 NYCRR §§ 709 with respect to the public need 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 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.

19.14 Monte 2.a.iv Title 10, 709.2

Background and justification provided in your request:

We seek a waiver of 709.2, which outlines the process for certificate of need applications involving the construction or establishment of new or replacement beds in an acute care hospital and the need for acute care facilities and services The HVC seeks this waiver for project 2.a.iv, creating a medical village using existing hospital infrastructure. To develop these three models, the HVC will need to undertake activities implicated under 709.2, namely construction to modify acute care facilities to meet the objectives of projects 2.a.iv. We request a waiver because the regulation, as currently constructed, could significantly delay the timeline for these activities and undermine the likelihood of meeting DSRIP project milestones. Further, we suggest that the comprehensive analysis and community health needs activities embedded in DSRIP fulfill many of the objectives of the determination for public need process. As an alternative, the HVC will need to revisit detailed project plans and potentially alter activities to no longer implicate 709.2, which may in turn diminish the extent of system transformation feasible.

Response to waiver request:

Bed Capacity. Approved. The PPS requested waivers involving changes in bed capacity. Waivers of 10 NYCRR §§ 710 and 401(e), pertaining to the CON process for changes in bed capacity, 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. The Department will expedite all DSRIP projects.

19.15 Monte 2.a.i.; 2.a.iii.; 2.a.iv.; 2.b.iii.; 3.a.i.; 3.a.ii.; 3.b.i.; 3.d.iii.; 4.b.i.; and 4.b.ii. Title 10, 710.1(c) Approval of Medical Facility Construction

Background and justification provided in your request:

We seek a waiver of 710.1(c), which concerns the erection, building, acquisition, alteration, reconstruction, improvement, extension or modification of a medical facility. The HVC seeks this waiver for projects 2.a.i.; 2.a.iii.; 2.a.iv.; 2.b.iii.; 3.a.i.; 3.a.ii.; 3.b.i.; 3.d.iii.; 4.b.i.; and 4.b.ii. As an illustration, five of the seven DSRIP counties in the HVC are designated Health Professional Shortage Areas (HPSAs); in these areas in particular, the HVC will build up primary care access and in some cases, construct new primary care facilities as a part of project 2.a.i. Further, all of the projects noted above require the expanded use of HIT technologies and interoperability, which will require investment in new EHR technologies, outlay of capital and the provision of vendor services. The reasons for the waiver request is to relieve the PPS and all partners from having to submit new certificate of need applications and receive prior review and approval for all DSRIP activities, including the physical modifications described above and HIT acquisition, installation, modification or outlay of capital. We request a waiver because the regulation, as currently constructed, could significantly delay the timeline for activities such as those outlined above and undermine the likelihood of meeting DSRIP project milestones.

Response to waiver request:

Public Need and Financial Feasibility. Approved. The PPS requested waivers involving certificate of need. Waivers for 10 NYCRR §§ 670.1, 709 and 710.2, with respect to the public need and financial feasibility components of the CON process, are approved, however, that:

- No waiver is available for establishment applications.
- Only the public need and financial feasibility components of the CON process are waived, meaning that a construction application still needs 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 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.

19.16 Monte 2.a.i Title 10, 711.1

Background and justification provided in your request:

We seek a waiver of 711.1, which notes that an applicant seeking approval to construct a new health facility or alter or renovate an existing health facility shall submit a completed application and functional program to the Department of Health. The HVC seeks this waiver for project 2.a.iv, creating a medical village using existing hospital infrastructure and project 2.a.i, the creation of an integrated delivery system based on evidence-based medicine. To develop this project, the HVC will need to submit applications to the Department of Health for the development of new facilities or alterations or renovations to those facilities. As an illustration, five of the seven DSRIP counties in the HVC are designated Health Professional Shortage Areas (HPSAs); in these areas, the HVC will build up primary care access and in some cases, construct new primary care facilities as a part of project 2.a.i. We request a waiver because the regulation, as currently constructed, could significantly delay the timeline for these activities and undermine the likelihood of meeting DSRIP project milestones.

Response to waiver request:

Construction Standards. Denied. The PPS requested waivers of §§ 711.1, 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.

19.17 Monte 2.a.iv Title 10, 712-1.11

Background and justification provided in your request:

We seek a waiver of 712-1.11, which proscribes physical parameters that hospital outpatient facilities must meet, such as size and types of structures and rooms included in the facilities. The HVC seeks this waiver for project 2.a.iv, creating a medical village using existing

hospital infrastructure. To develop this project, the HVC will likely modify outpatient hospital facilities to meet new purposes; for example, within an outpatient setting, the HVC may incorporate telephonic care management services, perhaps obviating the need for sterile supply storage. We seek a waiver because it is conceivable that project objectives, as determined through the community needs assessment and discussions with PPS partners, require a departure from the strict physical parameters proscribed in 712-1.11 such as in the instance above.

Response to waiver request:

Construction Standards. Denied. The PPS requested waivers of §§ 713-1.11 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.

19.18 Monte 2.a.iv Title 10, 86-1.31

Background and justification provided in your request:

We seek a waiver of 86-1.31, which outlines activities related to mergers, acquisitions, and consolidations. The HVC seeks this waiver for project 2.a.iv, creating a medical village using existing hospital infrastructure. As it stands 10 NYCRR 86-1.31 allows facilities to apply for temporary adjustment to the non-capital components of rates calculated pursuant to [such] Subpart for eligible general hospitals. Currently eligible general hospitals under this regulation must undergo a full asset merger in order to receive such adjustment. Montefiore believes that, in order to achieve truly transformational change under project 2.a.iv, disruptions and consolidations in the provider community are inevitable and, in order, to facilitate such changes, assistance must be available to those providers that acquire, consolidate or otherwise restructure provider systems. The restrictions of 10 NYCRR 86-1.31 stand as a barrier to such changes.

Response to waiver request:

Approved.

19.19 Monte

Background and justification provided in your request:

The prohibition on the corporate practice of medicine raises concerns since corporations may not employ licensed professionals to practice medicine. While we understand that this is not a state regulatory matter, we request that the Department of Health acknowledge, in consultation with Department of Education, that all PPS activities within HVC projects do not constitute the corporate practice of medicine under (1) Educ. Law 6522 which provides that only a person licensed or otherwise authorized under Education Law shall practice medicine and (2) Educ. Law 6527, which provides that a non-profit medical or dental expense indemnity corporation or a hospital service corporation may employ licensed physicians.

Response to waiver request:

Corporate Practice of Medicine. Denied. The PPS requested regulatory waivers in connection with the corporate practice of medicine, which is a statutory doctrine and therefore cannot be waived. This request is therefore denied. Please note, however, that the provision of health care services by an Accountable Care Organization (ACO) shall not be considered the

practice of a profession under Education Law Title 8, and a PPS may submit an application for an ACO certificate of authority. See 10 NYCRR § 1003.14(f); http://www.health.ny.gov/health_care/medicaid/redesign/aco/docs/faqs.pdf.

19.20 Monte 3.a.i, 3.b.ii Title 14, Chapter XIII, 551.6

Background and justification provided in your request:

We seek a waiver of 551.6, which outlines projects related to Office of Mental Health services that are subject to prior review before implementation. The HVC seeks this waiver for project 3.a.i, integration of primary care services and behavioral health, and 3.b.iii, behavioral health crisis stabilization. Under project 3.a.i, the HVC will cultivate three models: (1) the integration and co-location of mental health services into primary care clinics; (2) integration and co-location of primary care into mental health service providers; and (3) the collaborative care model (telephonic behavioral health services) at sites where physical co-location is not possible. To execute this project, we will need to in some cases modify primary care facilities to incorporate mental health services and vice versa. Under project 3.b.iii, we will expand crisis stabilization services where they exist and develop needed outpatient and inpatient mental health services. We intend to develop mobile crisis units staffed with clinical and peer staff to actively outreach to members in the community and provide urgent services. We are very concerned that the regulatory application and review process set forth in 551.6, including initial notification of local government units (LGUs), associated with the delivery of OMH-related services will delay the timeline for these activities and undermine the likelihood of achieving DSRIP milestones; we therefore request a waiver of this provision. As an alternative, the HVC will need to revisit detailed project plans and potentially alter activities to no longer implicate 551.6, which may in turn diminish the extent of system transformation feasible.

Response to waiver request:

More information needed. Please contact Keith McCarthy at OMH via email at Keith.McCarthy@omh.ny.gov. OMH supports any telepsychiatry services to be provide pursuant to the standards of the soon–to-be adopted regulation.

19.21 Monte 2.a.i., 2.a.iv.; 2.b.iii.; 3.a.i. and 3.a.ii 14 NYCRR 599.4 (ab)

Background and justification provided in your request:

We seek a waiver of 14 NYCRR 599.4 (ab) for projects 2.a.i., 2.a.iv.; 2.b.iii.; 3.a.i. and 3.a.ii. to permit Article 28 licensed providers to operate mental health services either within the general hospital or in an outpatient hospital department in amounts which exceed the current limits of visits annually. This exemption from requiring OMH licensure, regardless of the number of patients served, will help transform the method of delivering services and increase access to behavioral health and primary 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.

19.22 Monte 2.a.i; 2.a.iv.; 2.b.iii.; 3.a.i. and 3.a.i Title 14, 85.4

Background and justification provided in your request:

We seek a waiver of 14 NYCRR 85.4 for projects 2.a.i; 2.a.iv.; 2.b.iii.; 3.a.i. and 3.a.ii. to permit Department-regulated providers to operate mental health services under the oversight of the agency regulating them (the Department) and to forgo the requirements of an operating certification from OMH. One of the primary goals of DSRIP is to achieve better integration of primary care, behavioral health and/or substance use services. In some instances, this goal will best be accomplished through a single provider with single licensing agency at certain sites of service. We seek to remove or limit impediments to the provision of integrated services by licensed providers who seek to expand their scope of services in the context of integrated care models.

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.

19.23 Monte 2.a.i.; 2.a.iv.; 2.b.iii.; 3.a.i. and 3.a.i Title 14, 600.2

Background and justification provided in your request:

We seek a waiver of 14 NYCRR 600.2 for projects 2.a.i.; 2.a.iv.; 2.b.iii.; 3.a.i. and 3.a.ii. to permit behavioral and/or substance use providers to operate primary care under the oversight of the agency regulating them (OMH, OASAS or OPWDD) without the requirement of Department approval. One of the main DSRIP priorities is to stimulate the integration of primary care, behavioral health and/or substance use treatment services. This integration vision may be most efficiently accomplished through a single provider with single licensing agency at certain sites of service. We seek to remove or limit impediments to the provision of integrated services by licensed providers who seek to expand their scope of services.

Response to waiver request:

OPWDD response. More information is needed. If you are seeking a regulatory waiver to a OPWDD regulation, please resubmit request with specific regulatory citation, justification and description of impact on patient safety.

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.

19.24 Monte 2.a.i.; 3.a.i.; and 3.a.ii Title 14, 679.5

Background and justification provided in your request:

We seek a waiver of 14 NYCRR 679.5 for projects 2.a.i.; 3.a.i.; and 3.a.ii, to permit clinic treatment staff to conduct home visits and be eligible for reimbursement for services rendered within a patient's home.

The reason for this request is that in order to promote mental health services and reduce the reliance on ED and inpatient use, innovative methods of ensuring that patients receive necessary treatment are needed; one such strategy may include the provision of such services within the patient's home, recognizing transportation and physical mobility barriers.

Response to waiver request:

OMH- denied.14 NYCRR § 599.14. Per CMS, Medicaid will not reimburse for mental health services provided off-site.

19.25 Monte Title 14, Chapter XXI, 810 Establishment, Incorporation, Certification

Background and justification provided in your request:

We seek a waiver of 810, which outlines the establishment, incorporation, and certification of services related to Office of Alcoholism and Substance Abuse Services (OASAS) The HVC seeks this waiver for project 3.a.i, integration of primary care services and behavioral health, and 3.b.iii, behavioral health crisis stabilization. Under project 3.a.i, the HVC will cultivate three models: (1) the integration and co-location of OASAS services into primary care clinics; (2) integration and co-location of primary care into OASAS providers; and (3) the collaborative care model (telephonic behavioral health services) at sites where physical co-location is not possible. To execute this project, we will need to in some cases modify primary care facilities to incorporate mental health services and vice versa.

Under project 3.b.iii, we will expand crisis stabilization services where they exist and develop needed outpatient and inpatient OASAS services. We intend to develop mobile crisis units staffed with clinical and peer staff to actively outreach to members in the community and provide urgent services. We are very concerned that the regulatory application and review

process set forth in 810, including initial notification of local government units (LGUs), associated with the delivery of OASAS-related services will delay the timeline for these activities and undermine the likelihood of achieving DSRIP milestones; we therefore request a waiver of this provision.

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.

19.26 Monte Title 14, 814.7

Background and justification provided in your request:

We seek a waiver of 14 NYCRR 814.7 of projects 2.a.i; 2.a.iv.; 2.b.iii.; 3.a.i. and 3.a.ii. to permit partner organizations who locate services in shared space with OASAS providers flexibility in the physical requirements of the space provided there is adherence to federal regulations. One of the main DSRIP priorities is to transform patient care through integrating primary care, mental health services, and substance use treatment services. In order to collaborate and integrate, OASAS providers need to have flexibility to collaborate with other provides in their space and in the course of providing treatment. We seek to remove or limit impediments to the provision of integrated services.

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.

19.27 Monte Title 14, Parts 822 and 841

Background and justification provided in your request:

We request that the Department of Health work with the Centers for Medicaid and CHIP Services on a state plan amendment (SPA) to move OASAS services to the rehabilitation option of the SPA. This modification would permit Medicaid reimbursement of off-site providers to provide home visits. Once OASAS is authorized, we will request waivers of relevant sections in 14 NYCRR Parts 822 and 841 to request OASAS to authorize home visits for substance use treatment.

Response to waiver request:

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.

19.28 Monte Other

Background and justification provided in your request:

As the HVC engages in more extensive planning, we will request additional waivers that tie to more detailed project components. Potential future areas of inquiry include but are not limited to the following:

Title 10: Part 83 Shared Facilities (parts beyond sub-part 83.2(a)); 715 Freestanding Ambulatory Care Facilities; 415.38 Discharge (Ventilator Dependent Persons) Title 14: 590 Comprehensive Psychiatric Emergency Programs; 590.5 Certification; 590.9 Services; 599 Clinic Treatment Programs; 599.1 Integrated Services; 599.5 Certification; 36.4 Discharge of Inpatient Patients into Community Settings; Part 77 Physical Plant Standards for Behavioral Health Facilities; 504.5 Placement of Individuals Leaving Transitional Care Funding; Part 521 Financial Assistance for Construction or Acquisition of Behavioral Health Facilities; Part 573 Issuance of OMH Operating Certificates; Part 587 Standards for Operating Behavioral Health Outpatient Programs; Part 592 Governing Comprehensive Outpatient Programs; Part 595 Governing Operation of Adult Residential Programs Title 14, Chapter XXI: 810.5 Full Review; 810.6 Administrative Review; 814 General Facility; 814.2 Building Code Requirements; 814.3 Requirements of all Facilities; 814.6 Additional Requirements for OP Facilities; 840.8 Full Review Process; 810.9 Administrative Review Process; 816 Chemical Dependence Withdrawal and Stabilization Services; and 822 General Service Standards for Chemical services and Dependence Outpatient and Opioid Treatment; Part 321 Regarding Financing & Construction of OASAS Facilities; 815.7 Discharge from OASAS Services; Part 816 Inpatient and Outpatient Chemical Dependence Withdrawal and Stabilization; Part 819 Standards for Chemical Dependence Residential Services; Part 822-2 Outpatient Chemical Dependency and Opioid Treatment; Part 822-4 Staffing and Treatment Plans for Chemical Treatment Programs; Part 822-5 Opioid Treatment Programs.

Response to waiver request:

Not applicable as a specific regulatory waiver was not requested. The Department, OMH and OASAS will address Montefiore's additional regulation waiver requests as they are received.

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., 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

Kerry Delaney
Acting Commissioner
New York State Office for People With
Developmental Disabilities