



Department
of Health

Office of
Mental Health

Office of Alcoholism and
Substance Abuse Services

March 11, 2015

Mr. Arthur Gianelli
President
Mount Sinai St. Luke's Hospital
Mount Sinai Hospitals Group
MOUNT SINAI HOSPITAL
1111 Amsterdam Avenue
New York, New York 10025

Dear Mr. Gianelli:

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 Mount Sinai Hospital in its capacity as lead for the Mount Sinai Hospitals Group 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 Mount Sinai Hospitals Group PPS Project Plan application are addressed below.

34.01 Mount Sinai 2.a.i 10 NYCRR 86-4.9

Background and justification provided in your request:

All MSPPS selected projects will require the participation of sites with co-located services in order to seamlessly integrate services and achieve the goals of DSRIP. Specifically, the entire focus of Project 3.a.i is centered on the co-location of behavioral health and primary care services. The need for behavioral health services among the patient populations targeted in each project is pronounced, specifically the behavioral health population in Project 3.a.i and 3.a.iii, and additionally individuals with co-occurring behavioral health disorders targeted in Project 3.b.i (cardiovascular conditions), 3.c.i (diabetes), and 4.c.ii (HIV/AIDS). All projects require greater coordination of care and increased access to preventive care, which can be enhanced through co-located behavioral health, primary care, and other needed clinical services. Projects 2.b.iv and 2.b.viii require greater care coordination and increased access to services within a timeframe to prevent hospital readmissions for highly complex patient populations. These populations include individuals with co-morbidities, mobility issues and transportation barriers, and poor health literacy. The availability of co-located services in one-stop clinics will greatly increase the ability of care coordinators, case managers, and community health navigators to ensure patient adherence to care plans and access to needed services.

Single threshold regulations prohibit free-standing ambulatory care facilities from billing for more than one threshold visit per day. This applies to FQHCs as well as other clinics.

The Department should waive 86-4.9 limiting reimbursement to only one threshold visit per day, if the services provided on the same day if the services are of different types (e.g., medical, dental, and behavioral services should each be billable on a particular day), and the services are provided by an MSPPS member. Failure to modify this regulation will create a roadblock in accessing to behavioral health and other services types and inhibit the achievement of DSRIP outcomes.

Response to waiver request:

Integrated services. Approved solely with respect to 14 NYCRR 599.4(r) and (ab), which will be waived contingent upon following the DSRIP Project 3.a.i Licensure Threshold Model outlined in Appendix A to this letter. 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.

34.02 Mount Sinai 3.a.i, 3.a.iii, 3.b.i, 3.c.i, 4.c.ii -- 2.b.iv, 2.b.viii 14 NYCRR 599

Background and justification provided in your request:

14 NYCRR 599.2 prohibits the operation of outpatient programs for persons with mental illness without an operating certificate issued by the commissioner of mental health. 14 NYCRR 599.5(e)(1) requires satellite operations of clinics to be approved under Part 551. 14 NYCRR 599.5(f) and (g), require OMH approval for changing hours of operation or establishment of a new program. 14 NYCRR 599.14 should be waived as to the maximum number of payable claims per day (only three Medicaid claims per day are permitted) if the services are provided at a multi-disciplinary site and consist of a mix of services. Any expansion site operating at a site approved to provide medical or health services or substance abuse services should be deemed approved under Section 551 and satisfying the applicable 599 requirements.

Response to waiver request:

More information needed by OMH. Clarification necessary relative to whether this is an Article 28 adding mental health services, or an Article 31 adding primary care services. Please email Keith McCarthy of OMH with such information at Keith.McCarthy@omh.ny.gov.

Approved relative to the PAR process for ascertaining “need” and “financial feasibility”, but a PAR is necessary to formalize any licensing changes.

Denied relative to 599.14.

34.03 Mount Sinai 2.b.viii 10 NYCRR 762.2 (specifically, 762.2(c))

Background and justification provided in your request:

See Hospice Operation - General Provisions. 10 NYCRR 762.2 requires a certified home health agency or a long term home health care program to obtain approval for a change in the program’s geographic service area. This requirement should be waived for any agency that participates in the MSPPS, and that receives a patient referred by another MSPPS member in which the agency and the MSPPS member are engaged in a care coordination program.

Response to waiver request:

Expansion of home care geographic service area. Determination pending.

34.04 Mount Sinai 2.b.viii 10 NYCRR 791.2

Background and justification provided in your request:

The goal of Project 2.b.viii is to reduce 30-day hospital readmissions for Medicaid beneficiaries discharged into home care. Through care coordination and wrapping the target patient population with all needed services, including hospice and palliative care, the project will address patients’ underlying health and social service needs that drive hospital readmissions. Hospice and palliative care services that reduce patient pain and discomfort are key to better meeting the needs of this population, but are lacking within the service area. In addition, in order to integrate services across the entire service area as required by DSRIP and Project 2.a.i, hospice providers will need the flexibility to serve patients within the entire MSPPS service area. 10 NYCRR 791.2 requires a hospice to obtain approval for any change to its geographic service area. This requirement should be waived for a hospice that participates in the MSPPS, and that receives a patient referred by another MSPPS member in which the hospice and the MSPPS member are engaged in a care coordination program.

Response to waiver request:

Expansion of hospice geographic service area. Determination pending.

34.05 Mount Sinai 10 NYCRR 86-4.9(i)

Background and justification provided in your request:

A key goal of DSRIP is to provide patients with the right care, at the right time, and in the right place. All Mount Sinai PPS selected projects will require the participation of clinical sites that have the flexibility to serve patients that may not have the capacity to receive care onsite. These patients may be too sick, frail, and/or lack transportation to visit a clinic. Regulations prohibit payment for FQHC services if provided to patients whose status is expected to permanently preclude return to the FQHC. Regulations also limit the provision of off-site services to physicians, PAs, midwives and nurse practitioners. FQHCs should have flexibility to offer services to patients who may not return to on-site status, and also to offer off-site services of dental providers, social workers and nurses. Failure to modify this regulation will hinder the ability of key DSRIP primary care providers from serving populations with the highest level of needs and least access to care.

Response to waiver request:

OHIP drafting response - Will look at flexibility of 86-4.9

34.06 Mount Sinai 3.a.i, 3.a.iii, 3.b.i, 3.c.i, 4.c.ii -- 2.b.iv, 2.b.viii 10 NYCRR Part 600

Background and justification provided in your request:

All MSPPS selected projects will require the participation of sites with co-located services in order to seamlessly integrate services and achieve the goals of DSRIP. Specifically, the entire focus of Project 3.a.i is centered on the co-location of behavioral health and primary care services. The need for behavioral health services among the patient populations targeted in each project is pronounced, specifically the behavioral health population in Project 3.a.i and 3.a.iii, and additionally individuals with co-occurring behavioral health disorders targeted in Project 3.b.i (cardiovascular conditions), 3.c.i (diabetes), and 4.c.ii (HIV/AIDS). All projects require greater coordination of care and increased access to preventive care, which can be enhanced through co-located behavioral health, primary care, and other needed clinical services. Projects 2.b.iv and 2.b.viii require greater care coordination and increased access to services within a timeframe to prevent hospital readmissions for highly complex patient populations. These populations include individuals with co-morbidities, mobility issues and transportation barriers, and poor health literacy. The availability of co-located services in one-stop clinics will greatly increase the ability of care coordinators, case managers, and community health navigators to ensure patient adherence to care plans and access to needed services. The addition of any primary care, behavioral or substance abuse services by a licensed MSPPS participant should not be required to establish need or prove financial feasibility under 10 NYCRR Part 600 or 670. In order to implement DSRIP projects within the prescribed timeframe, service providers will need to adapt quickly and meet an increased demand for behavioral health. The time consuming effort of demonstrating the financial feasibility of a project required to obtain a Certificate of Need is not realistic within the given timeframe of implementation. Furthermore, financial feasibility of most DSRIP projects will be based not only

on the ability of the entire PPS to achieve DSRIP outcomes, but also on statewide DSRIP outcomes.

Response to waiver request:

Integrated services. Approved solely with respect to 14 NYCRR 599.4(r) and (ab), which will be waived contingent upon following the DSRIP Project 3.a.i Licensure Threshold Model outlined in Appendix A to this letter. 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.

34.07 Mount Sinai 3.a.i, 3.a.iii, 3.b.i, 3.c.i, 4.c.ii -- 2.b.iv, 2.b.viii 10 NYCRR Part 703

Background and justification provided in your request:

Pursuant to 703.2, Article 31 or Article 32 facilities must meet all of the requirements of Chapter V of the Department regulations (i.e., all CON, licensure and related regulations applicable to Article 28 sites. Any licensed MHL Article 31 or Article 32 provider that adds ambulatory health care services (provided that such services are less than half of the services offered at the applicable location) should not be required to independently satisfy the requirements of 10 NYCRR 703.2, 703.3, 703.4, and 703.6. In order to co-locate services through Project 3a.i and integrate care across the delivery system to meet the requirement of all DSRIP projects, Article 31 and 32 licensed facilities will need to add primary care. To do so within the given timeframe of DSRIP, they should not have to independently meet A28 requirements.

Response to waiver request:

Integrated services. Approved solely with respect to 14 NYCRR 599.4(r) and (ab), which will be waived contingent upon following the DSRIP Project 3.a.i Licensure Threshold Model outlined in Appendix A to this letter. 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.

34.08 Mount Sinai 10 NYCRR Part 710

Background and justification provided in your request:

We anticipate that integrating the delivery system through Project 2.a.i will require a significant restructuring of the MSPPS health care infrastructure and a shift care from costly inpatient hospital use to outpatient care. This will require downsizing of provider capacity based on a systematic formal analysis of excess beds. Approval of new Article 28 Facility construction in conjunction with downsizing should be limited to administrative review 10 NYCRR 710.1(c)(2) and (3), provided that no new services are added that are specified in 710.1(c)(2)(i)(b). In order to implement DSRIP projects within the prescribed timeframe and achieve DSRIP, hospitals will need implement infrastructure changes that will drive this shift in the delivery of care quickly. Limiting downsizing of Article 28 construction to administrative review will ensure that this shift occurs.

Response to waiver request:

Bed Capacity. Approved. The PPS requested a waiver of 10 NYCRR §§ 710), pertaining to the CON process for changes in bed capacity. This request is 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.

34.09 Mount Sinai 10 NYCRR Part 710

Background and justification provided in your request:

Limited review (10 NYCRR Part 710.1(c)(5) should be applied to:

- The integration of mental health services into an already established site providing medical or health services, and such review should substitute for other agency review.
- Any expenditures for health information technology. For projects that require construction, if the construction is limited making changes to the floor plan consistent with co-location of health and mental health services, permit self-certification of architectural approvals (10 NYCRR 710.4 and 710.6) and provide for waiver or presumptive approval of inspections (10 NYCRR 710.9).

Response to waiver request:

Integrated services. Approved solely with respect to 14 NYCRR 599.4(r) and (ab), which will be waived contingent upon following the DSRIP Project 3.a.i Licensure Threshold Model outlined in Appendix A to this letter. 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.

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.

34.10 Mount Sinai 2.a.i 10 NYCRR Part 710 and 10 NYCRR 401.3(e)

Background and justification provided in your request:

Decertification of services or bed reductions should be subject only to limited review, regardless of scope or expense of project. Also requires waiver of 10 NYCRR 401.3(e).

Response to waiver request:

Bed Capacity. Approved. The PPS requested waivers of 10 NYCRR §§ 710 and 401.3(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. The Department will expedite all DSRIP projects.

34.11 Mount Sinai 2.a.i, 2.b.iv, and 4.b.ii 10 NYCRR Part 86 Subpart 86-1

Background and justification provided in your request:

All MSPPS selected projects will require the development of a clinically integrated health system with seamless coordination of care. In particular, Projects 2.a.i, 2.b.iv, and 4.b.ii will drive a restructuring of hospital services to improve population health by serving outpatient needs in the community while increasing access to specialized services requiring an inpatient setting. Over time, this will result in the reduction of excess hospital capacity, supporting a focus on providing high quality evidence-based inpatient care when medically appropriate.

Consistency of financial reimbursement for services to Medicaid patients across the MSPSS will be essential to achieving the necessary facility restructuring and integration. A clarification of 10 NYCRR 86-1.31 would support MSPPS's hospital partners in achieving this consistency. General hospitals joining under the common control of the same active parent entity for purposes of creating a more economical common enterprise should qualify as a merger, acquisition and consolidation as used in 10 NYCRR 86-1.31. Payments for such hospitals should be calculated based on the Subpart 86-1 rate factors of the hospital with the highest pre-combination rate. This would allow all combining hospitals to operate under consistent reimbursement rates while reinforcing the Department's commitment to supporting providers during this period of system transformation.

Response to waiver request:

Determination pending.

34.12 Mount Sinai 3.a.i, 3.a.iii, 3.b.i, 3.c.i, 4.c.ii -- 2.b.iv, 2.b.viii 14 NYCRR 551

Background and justification provided in your request:

See Medical Assistance Payment to Outpatient Programs Permit existing providers of behavioral health services to add additional locations (provided that such locations are licensed under Articles 31 or 32 of the MHL or Article 28 of the PHL), without undergoing regulatory review. Specifically, waive 551.2(a) requiring an operating certificate. Expansion to primary care sites should be automatic if a component of an approved MSPPS project.

Section 551.6(c) approvals related to program changes should be waived pertaining to such satellite clinics. Section 551.6(d) regarding changes in program location should be waived.

Response to waiver request:

Integrated services. Approved solely with respect to 14 NYCRR 599.4(r) and (ab), which will be waived contingent upon following the DSRIP Project 3.a.i Licensure Threshold Model outlined in Appendix A to this letter. 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.

34.13 Mount Sinai 3.a.i, 3.a.iii, 3.b.i, 3.c.i, 4.c.ii -- 2.b.iv, 2.b.viii 14 NYCRR 587

Background and justification provided in your request:

587.2(b) prohibits outpatient programs without an operating certificate. This will limit the ability to open new programs through the coordination of two existing already-licensed providers.

587.5(h) limits changes in physical space, location, use of additional sites and change in capacity. These requirements should be waived to permit joint programs among already-licensed providers under PHL Article 28, or MHL 31 and/or 32. For the purpose of calculation of staffing requirements under 14 NYCRR 587.15, to allow for flexible staffing at multiple sites, staffing ratios should be consolidated to central service site. (Patient safety should not be adversely affected because staffing ratios will still be maintained at the provider, and the remote site will be co-located with another licensed provider entity).

Response to waiver request:

Integrated services. Approved solely with respect to 14 NYCRR 599.4(r) and (ab), which will be waived contingent upon following the DSRIP Project 3.a.i Licensure Threshold Model outlined in Appendix A to this letter. 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.

34.14 Mount Sinai 3.a.i, 3.a.iii, 3.b.i, 3.c.i, 4.c.ii -- 2.b.iv, 2.b.viii 14 NYCRR 588.5

Background and justification provided in your request:

14 NYCRR Part 588.5 is a provision that requires, among other things, that any program should have a valid operating certificate issued by OMH. To effectively co-locate services and provide behavioral health services at a primary care site, not only must providers comply with the substantive requirements of Part 587, but they will not be paid for services unless they meet the requirements of 588. No OMH operating certificate should be required for a location whose expansion or operation is approved due to waivers pursuant to an approved DSRIP program in order for the applicable program to receive reimbursement.

Response to waiver request:

Integrated services. Approved solely with respect to 14 NYCRR 599.4(r) and (ab), which will be waived contingent upon following the DSRIP Project 3.a.i Licensure Threshold Model outlined in Appendix A to this letter. 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.

34.15 Mount Sinai 3.c.i 10 NYCRR & 401.2 (b)

Background and justification provided in your request:

This will assist us to see home-bound patients and better manage their diabetes.

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

34.16 Mount Sinai 2.a.i, 3.a.i, 3.a.iii Article 31

Background and justification provided in your request:

Will provide flexibility to serve individuals who are either home bound or are not ready to engage in treatment outside their home.

Response to waiver request:

Denied. This is a federal prohibition and we do not have the authority to waive federal requirements.

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.

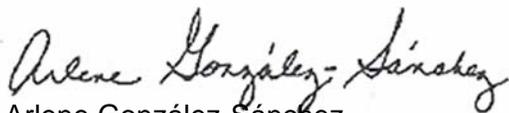
Sincerely,



Howard 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