



**Department
of Health**

**Office of
Mental Health**

**Office of Alcoholism and
Substance Abuse Services**

February 20, 2015

The New York Hospital Medical Center of Queens
NEW YORK HOSP MED CTR QUEENS
Maureen Buglino, RN,
VP Community Medicine & Emergency Medicine
56-45 Main St
Flushing, NY 11355

Dear Ms. Buglino

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 The New York Hospital Medical Center of Queens in its capacity as lead for The New York Hospital Medical Center of Queens 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 New York Hospital Medical Center of Queens PPS Project Plan application are addressed below.

40.01 NY QUEENS 2.a.ii, 3.a.i 10 N.Y.C.R.R. § 710.1(c)(1)

Background and justification provided in your request: Project 2.a.ii- Increase certification of primary care practitioners with PCMH certification and/or Advanced Primary Care. Project 3.a.i - Integration of Primary Care and Behavioral Health Services. Regulation to be waived is: Certificate of need review required for opening of an extension clinic, including a mobile health unit, or expansion of the capacity of an established facility.

Components that are impacted: Increase Primary Care Practitioners with PCMH Certification and/or Advanced Primary Care in northwestern Queens; Integration of Primary Care and Behavioral Health Services

The NYHQ PPS Community Needs Assessment established the shortage of primary care and behavioral health providers in the Northwest Queens, consisting of zip codes 11368 Corona, 11355 Flushing, 11373 Elmhurst, 11377 Woodside, and 11385 Ridgewood. Expansion of the capacities of Mental Health Providers of Western Queens and HELP/PSI Queens Health Center are likewise necessary to facilitate integration of primary care and behavioral health within the PPS. Accomplishment of the requirements of projects 2.a.ii and 3.a.i will be impaired if the PPS partners are unable to cover the attributed Medicaid beneficiaries and those eligible throughout PPS's entire geographic area with respect to these projects.

Response to waiver request:

Public Need and Financial Feasibility. Approved. The PPS requested a waiver with respect to the public need and financial feasibility components of the CON process. A waiver for 10 NYCRR §§ 710.2 is approved, however, that:

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

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

**40.02 NY QUEENS 3.a.i 10 N.Y.C.R.R. § 401.2(b) 10 N.Y.C.R.R. § 401.1(d) 10
N.Y.C.R.R. § 401.3(d)**

Background and justification provided in your request: Project 3.a.i - Integration of Primary Care and Behavioral Health Services. Regulations to be waived are: Requiring an operating certificate to be used only by the established operator for the designated site of operation, with a temporary exception for emergencies; Requiring Article 28 facilities to be physically, administratively, and financially independent and distinct from other operations of any other provider or health facility, and Prohibiting Article 28 providers from leasing or subleasing a portion of that facility to a non-Article 28 facility. Components that are impacted: Integration of primary, specialty, behavioral, and social care services through the co-location of primary care practitioners and Article 28, 31 & 32 facilities.

Under the DSRIP program, a provider established under either Article 28, Article 31, or Article 32 may provide primary care and behavioral health services under their single license. Two or more such established providers may also share space pursuant to an approved, written plan. To facilitate the implementation of this project, approval is hereby requested for project plan 3.A.I as the written plan permitting the co-location of Article 28, 31, and/or 32 providers. Waiver of 10 N.Y.C.R.R. § 401.2(b) is requested to permit the Article 28, 31 & 32 providers to provide services outside of their designated sites of operation. Waiver of 10 N.Y.C.R.R. § 401.3(d) is requested to permit NYHQ to lease space to physician members of the PPS to supplement and coordinate with the services currently available at its designated sites of operation.

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.

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.

40.03 NY QUEENS

10 N.Y.C.R.R. § 710.1(c)(3)(h)

Background and justification provided in your request: Project 3.d.ii - Expansion of asthma home-based self-management. Regulation to be waived is: Requiring administrative review for the relocation of an extension clinic (in this case the Mobile Asthma Van) to a site outside of the current service area of the extension clinic that does not include an increase in scope of services or clinical capacity. Components that are impacted: Expansion of service area of NYHQ Mobile Asthma Van

NYHQ currently has authorization to operate a Mobile Asthma Van. The Mobile Van has the capacity to perform many of the services that are instrumental to the accomplishment of the project requirements of Project 3.d.ii. Expansion of the service area of the Mobile Asthma Van is the most effective and efficient method to deliver those services to areas of high need, and the requirement to complete administrative review will delay implementation of this project.

Response to waiver request:

Approved contingent upon the provider submitting a limited review application through NYSE-CON.

In cases where waivers are approved, the agencies will send letters directly to the providers which otherwise would be responsible for complying with the regulatory provisions at issue. Providers further will be advised that State 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

Arlene González-Sánchez
Commissioner
New York State Office of Alcoholism
And Substance Abuse Services

Attachment A
DSRIP Project 3.a.i Licensure Thresholds

Guidance for DSRIP Performing Provider Systems Integrating Primary Care and Behavioral Health (Mental Health and/or Substance Use Disorder) Services under Project 3.a.i

Background

Generally, to offer both primary care and behavioral health services (meaning mental health and/or substance use disorder services), a provider must be licensed or certified by more than one state agency (Department of Health, Office of Mental Health or Office of Alcoholism and Substance Abuse Services), unless they fall under the applicable “Licensure Threshold.”

In order to facilitate integration of primary care and behavioral health services for purposes of Project 3.a.i, the Department of Health (DOH) and the Office of Mental Health (OMH) will raise their Licensure Thresholds and the Office of Alcoholism and Substance Abuse Services (OASAS) will implement a Licensure Threshold for outpatient providers licensed or certified by DOH, OMH or OASAS that are part of the DSRIP project, permitting such providers to integrate primary care and behavioral health services under a single license or certification so long as the service to be added is not more than 49 percent of the provider’s total annual visits (“DSRIP Project 3.a.i Licensure Threshold”) and the patient initially presents to the provider for a service authorized by such provider’s license or certification.

In order to help ensure quality care and patient safety, providers that wish to integrate services between the existing Licensure Threshold and the DSRIP Project 3.a.i Licensure Threshold will be expected to be in good standing and adhere to prescribed sections of the integrated outpatient regulations -- 10 NYCRR Part 404, 14 NYCRR Part 598 and 14 NYCRR Part 825.

A. Primary Care Provider Offering Mental Health Services

Existing Licensure Threshold

Currently, a provider licensed under PHL Article 28 and offering mental health services – meaning a general hospital outpatient department or a diagnostic and treatment center (primary care provider) – and which has more than 2,000 total visits per year must be licensed under Article 31 of the Mental Hygiene Law (MHL) by OMH if it has **more than 10,000 annual visits** for mental health services or **more than 30 percent of its total annual visits** are for mental health services.

DSRIP Project 3.a.i Licensure Threshold

OMH will raise this Licensure Threshold for DSRIP providers participating in 3.a.i projects so that primary care providers may provide **up to 49 percent of its total annual visits** for mental health services without MHL Article 31 licensure.

Attachment A
DSRIP Project 3.a.i Licensure Thresholds

Prescribed Regulatory Requirements

In addition to being in compliance with applicable PHL Article 28 requirements, DSRIP providers integrating services between the existing Licensure Threshold and the DSRIP Project 3.a.i Licensure Threshold will need to meet the prescribed regulatory requirements of DOH's integrated outpatient services regulations – 10 NYCRR Part 404:

- 10 NYCRR 404.4(f), which defines “integrated care services.”
- 10 NYCRR 404.6(b), which provides the governing board’s oversight responsibilities with respect to the provider integrating services.
- 10 NYCRR 404.7(c)(1), (c)(2), (e) and (f), which require treatment planning for any patient receiving behavioral health services from an integrated services provider.
- 10 NYCRR 404.8(a), (b), (c), (d), (e), (f), (g), (i), (j) and (l), which identify minimum policies and procedures for integrated services providers.
- 10 NYCRR 404.9(b)(2)(i), (b)(2)(ii)(b) and (b)(2)(iii), which identify the minimum services required of providers that will be integrating mental health care services.
- 10 NYCRR 404.10(c)(1)(iv) and (c)(1)(vii), which provide general facility requirements for individual and group sessions and maintenance of records and confidentiality of all patient information.
- 10 NYCRR 404.11(a)(2)(i) and (a)(2)(ii), which require providers integrating mental health services to comply with quality assurance requirements under 14 NYCRR Part 599.
- 10 NYCRR 404.13(a), (d)(1), (d)(2)(ii) and (d)(11), which require that a record be maintained for every individual admitted to and treated by a provider integrating services and be able to accept consent forms, if applicable. Additional requirements include minimum content fields specific to each model.

B. Primary Care Provider Offering Substance Use Disorder Services

Existing Licensure Threshold

Currently, there are no Licensure Thresholds. A primary care provider may not provide substance use disorder services without being certified by OASAS pursuant to MHL Article 32.

DSRIP Project 3.a.i Licensure Threshold

OASAS will implement a Licensure Threshold for DSRIP providers participating in 3.a.i projects so that primary care providers may provide **up to 49 percent of its total annual visits** for substance use disorder services without MHL Article 32 certification.

Attachment A
DSRIP Project 3.a.i Licensure Thresholds

Prescribed Regulatory Requirements

In addition to being in compliance with applicable PHL Article 28 requirements, DSRIP providers integrating substance use disorder services up to the DSRIP Project 3.a.i Licensure Threshold will need to meet the prescribed regulatory requirements of DOH's integrated outpatient services regulations – 10 NYCRR Part 404:

- 10 NYCRR 404.4(f), which defines “integrated care services.”
- 10 NYCRR 404.6(b), which provides the governing board’s oversight responsibilities with respect to the provider integrating services.
- 10 NYCRR 404.7(c)(1), (c)(2), (e) and (f), which require treatment planning for any patient receiving behavioral health services from an integrated services provider.
- 10 NYCRR 404.8(a), (b), (c), (d), (e), (f), (g), (i), (j) and (l) which identify minimum policies and procedures for integrated services providers.
- 10 NYCRR 404.9(c)(4), which identifies the minimum services required of providers that will be integrating substance use disorder services.
- 10 NYCRR 404.10(c)(1)(iv) and (c)(1)(vii), which provide general facility requirements for individual and group sessions and maintenance of records and confidentiality of all patient information.
- 10 NYCRR 404.11(a)(2)(i) and (a)(2)(ii), which require providers integrating substance use disorder services to comply with quality assurance requirements under 14 NYCRR Part 822.
- 10 NYCRR 404.12(c)(2), which provides staffing requirements for providers offering substance use disorder services.
- 10 NYCRR 404.13(a), (d)(1), (d)(2)(iii), (d)(11) and (f)(2), which require that a record be maintained for every individual admitted to and treated by a provider integrating services and be able to accept consent forms, if applicable. Additional requirements include minimum content fields specific to each model.

C. Behavioral Health Services Provider Offering Primary Care Services

Existing Licensure Threshold

Currently, a provider licensed by OMH under MHL Article 31 to provide outpatient mental health services or certified by OASAS under MHL Article 32 to provide outpatient substance use disorder services must obtain PHL Article 28 licensure by DOH if **more than 5 percent of total annual visits** are for primary care services or if any visits are for dental services.

DSRIP Project 3.a.i Licensure Threshold

Attachment A
DSRIP Project 3.a.i Licensure Thresholds

DOH will raise this Licensure Threshold for DSRIP providers participating in 3.a.i projects so that a behavioral health services provider may provide **up to 49 percent of its total annual visits** for primary care services without PHL Article 28 licensure.

Prescribed Regulatory Requirements

In addition to being in compliance with applicable MHL Article 31 or 32 requirements, DSRIP providers integrating services between the existing Licensure Threshold and the DSRIP Project 3.a.i Licensure Threshold will need to meet the prescribed regulatory requirements of OMH or OASAS' integrated outpatient services regulations – 14 NYCRR Part 598 or 14 NYCRR Part 825, respectively:

- 14 NYCRR 598.4(f) and (j) or 14 NYCRR 825.4(f) and (j), which define “integrated care services” and “primary care services.”
- 14 NYCRR 598.6(b) or 14 NYCRR 825.6(b), which provides the governing board’s oversight responsibilities with respect to the integrated services provider.
- 14 NYCRR 598.8 (c), (d), (e), (g), (i), (j), (k), (l), (m), (n) and (o) or 14 NYCRR 825.8(c), (d), (e), (g), (i), (j), (k), (l), (m), (n) and (o), which identify minimum policies and procedures for integrated services providers.
- 14 NYCRR 598.9(a) or 14 NYCRR 825.9(a), which identifies the minimum services required of providers that will be integrating primary care services.
- 14 NYCRR 598.10 or 14 NYCRR 825.10, which provides minimum physical plant requirements for facilities integrating services.
- 14 NYCRR 598.11(a)(1) or 14 NYCRR 825.11(a)(1), which requires providers integrating primary care services to ensure the development and implementation of a written quality assurance program.
- 14 NYCRR 598.12(a), (b) and (c)(1) or 14 NYCRR 825.12(a), (b) and (c)(1), which provide staffing requirements.
- 14 NYCRR 598.13(a), (c), (d)(1), (d)(2)(i), (d)(10), (d)(11), (e) and (f) or 14 NYCRR 825.13(a), (c), (d)(1), (d)(2)(i), (d)(10), (d)(11), (e) and (f), which require that a record be maintained for every individual admitted to and treated by a provider integrating services. Additional requirements include designated record keeping staff, record retention and minimum content fields specific to each model. Confidentiality of records is assured via patient consents and disclosures compliant with state and federal law.

D. Mental Health Services Provider Offering Substance Use Disorder Services and Substance Use Disorder Services Provider Offering Mental Health Services

Existing Licensure Threshold

Currently, there are no Licensure Thresholds. However, programs licensed by OMH or certified by OASAS currently are able to integrate mental health and substance use disorder services with certain limitations pursuant to a Memorandum of Agreement between the agencies.

Attachment A
DSRIP Project 3.a.i Licensure Thresholds

DSRIP Project 3.a.i Licensure Threshold

OMH licensed and OASAS certified providers may continue to integrate mental health and substance use disorder services **up to 49 percent of their total annual visits.**

Prescribed Regulatory Requirements

DSRIP providers integrating mental health and substance use disorder services will need to be in compliance with applicable MHL Article 31 or 32 requirements. In addition, such providers will need to meet the prescribed regulatory requirements of OMH or OASAS' integrated outpatient services regulations – 14 NYCRR Part 598 and 14 NYCRR Part 825, respectively:

- 14 NYCRR 598.4(f) or 14 NYCRR 825.4(f), which defines “integrated care services.”
- 14 NYCRR 598.6(b) or 14 NYCRR 825.6(b), which provides the governing board’s oversight responsibilities with respect to the integrated services provider.
- 14 NYCRR 598.8(c), (d), (e), (g) and (i) or 14 NYCRR 825.8(c), (d), (e), (g) and (i), which identify minimum policies and procedures for integrated services providers.
- 14 NYCRR 598.9(c) or 14 NYCRR 825.9(b), which identifies the minimum services required of providers that will be integrating mental health or substance use disorder services.
- 14 NYCRR 598.12(c)(2), which provides staffing requirements for OMH licensed providers integrating substance used disorder services.
- 14 NYCRR 598.13(a), (d)(1), (d)(2)(iii) and (d)(11) or 14 NYCRR 825.13(a), (d)(1), (d)(2)(ii) and (d)(11), which require that a record be maintained for every individual admitted to and treated by a provider integrating services and be able to accept consent forms, if applicable. Additional requirements include minimum content fields specific to each model.

Above DSRIP Project 3.a.i Licensure Thresholds

When a provider believes its volume of services will approach the DSRIP Project 3.a.i Licensure Threshold limits outlined above, a provider has the option of integrating services by either seeking a second license for a particular site or integrating services under the integrated outpatient services regulations (see 10 NYCRR Part 404, 14 NYCRR Part 598 and 14 NYCRR Part 825). Providers that elect to integrate services under the integrated outpatient regulations will need to comply with all applicable provisions.

Attachment A
DSRIP Project 3.a.i Licensure Thresholds

Providers may not bill Medicaid for any service rendered above the DSRIP Project 3.a.i Licensure Threshold amount unless the appropriate licensure or certification is in place at the time the service was rendered.

Requirements

Providers that are interested in integrating services under a single license will need to submit an application to the Department of Health, which will be available soon, so that DOH, OMH and OASAS will, among other things, be able to:

- identify the outpatient provider and its sites that will be integrating services under the Licensure Thresholds;
- ascertain the services to be added;
- project the annual visits for the services that will be integrated at a provider site;
- verify that the provider integrating services is in good standing. A provider is in good standing if each clinic site:
 - is licensed by OMH and has been operating for a period of 1 year or greater as documented on the operating certificate (Tier 3 providers are not in good standing for purposes of these requirements); and/or
 - is certified by OASAS and all of its programs have an operating certificate with partial or substantial compliance (2 or 3 years); and/or
 - has an operating certificate from DOH and is not currently under any enforcement action or pending enforcement;
- if applicable, review floor plans and other physical plant issues.

Billing Guidance

Providers integrating services under the DSRIP 3.a.i Licensure Threshold should submit one claim for each visit with all the procedures/services rendered on the date of service (e.g., behavioral health services and primary care services). Provider clinic payment will be processed through the APG grouper/pricer and paid in accordance with the payment blend and APG pricing rules (packaging, discounting, bundling) associated with services normally billed under that APG rate code. Providers are expected to adhere to the licensure threshold limits identified in the table below. Providers may use a modifier to indicate when a separate and distinct procedure is performed (e.g., Procedure Modifier 59) in accordance with the American Medical Association's approved coding/billing guidelines for the procedures/services coded supported by appropriate documentation that justifies the modifier selected. Federally Qualified Health Centers that have not opted into APGs should bill their all-inclusive PPS rate of all services furnished to a patient on the same day.

Attachment A
DSRIP Project 3.a.i Licensure Thresholds

LICENSURE THRESHOLDS

Existing Licensure Thresholds	DSRIP Project 3.a.i Licensure Thresholds
A PHL Article 28 provider that has more than 2,000 total visits per year must be licensed by OMH if it has more than 10,000 annual visits for mental health services or more than 30 percent of its total annual visits are for mental health services.	A PHL Article 28 provider that has more than 2,000 total visits per year must be licensed by OMH if more than 49 percent of its total annual visits are for mental health services.
No existing Licensure Threshold. A PHL Article 28 provider may not provide substance use disorder services without being certified by OASAS pursuant to MHL Article 32.	A PHL Article 28 provider must be certified by OASAS if more than 49 percent of its total annual visits are for substance use disorder services.
A MHL Article 31 provider or MHL Article 32 must be licensed by DOH if more than 5 percent of its total annual visits are for primary care services or if any visits are for dental services.	A MHL Article 31 provider or MHL Article 32 must be licensed by DOH if more than 49 percent of its total annual visits are for primary care services or if any visits are for dental services.
No existing Licensure Threshold. A MHL Article 31 provider or MHL Article 32 is able to integrate mental health and substance use disorder services pursuant to a Memorandum of Agreement between OMH and OASAS.	<p>A MHL Article 31 provider must be certified by OASAS if more than 49 percent of its total annual visits are for substance use disorder services.</p> <p>A MHL Article 32 provider must be certified by OMH if more that 49 percent of its total annual visits are for mental health services.</p>