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

February 20, 2015

Refuah Health Center
REFUAH HEALTH CENTER INC
Chanie Sternberg, President & C.E.O.
728 North Main Street
Spring Valley, New York 10977

Dear Ms. Sternberg:

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 Refuah Health Center, Inc. in its capacity as lead for the Refuah Health Center 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, the Department, OMH, and OASAS may waive regulations for the purpose of allowing applicants to avoid duplication of requirements and to allow the efficient implementation of the proposed projects. However, the agencies may not waive regulations pertaining to patient safety nor waive regulations if such waiver would risk patient safety. Further, any waivers approved under this authority may not exceed the life of the project or such shorter time periods as the authorizing commissioner may determine.

Accordingly, any regulatory waivers approved herein are for projects and activities as described in the Project Plan application and any implementation activities reasonably associated therewith. Such regulatory waivers may no longer apply should there be any changes in the nature of a project. It is the responsibility of the PPS and the providers that have received waivers to notify the relevant agency when they become aware of any material change in the specified project that goes beyond the scope of which the waiver was granted. Further, any regulatory waivers approved are only for the duration of the projects for which they were requested.

The approval of regulatory waivers are contingent upon the satisfaction of certain conditions. In all cases, providers must be in good standing with the relevant agency or agencies. Other conditions may be applicable as set forth in greater detail below. The failure to satisfy any such conditions may result in the withdrawal of the approval, meaning that the providers will be required to maintain compliance with the regulatory requirements at issue and could be subject to enforcement absent such compliance.

Specific requests for regulatory waivers included in the Refuah Health Center PPS Project Plan application are addressed below.

20.01 Refuah 3.a.i, 2.a.ii 14 NYCRR Part 551 14 NYCRR Part 599.3

Background and justification provided in your request: The PPS will seek a waiver of 14 NYCRR Part 551 in order to co-locate behavioral health in an Article 28 clinic that is not also licensed by OMH under Article 31. It will also seek a waiver of 14 NYCRR Part 599.3 for Article 31 providers seeking to expand primary care services above the 5% of annual visits threshold.

This regulatory relief is being sought for two RCHC projects: 3.a.i and 2.a.ii. For Project 3.a.i, one of the primary components of the behavioral health (BH) co-located in primary care model is to institute a universal screening for behavioral health and substance abuse. The screenings are intended to identify behavioral health needs among primary care patients. Once identified, primary care sites must be able to meet these behavioral health needs, which, for most Article 28 primary care sites, will necessitate increasing the amount of behavioral health care they provide. Additionally, co-location is restricted by the volume limits imposed by licensure. These limits restrict providers' ability to implement the co-location and full integration models allowable for this project unless they hold both licenses. Current volume limits need to be increased or waived for RCHC's Article 28 partners in order to allow them to integrate behavioral health services in a meaningful way. For Project 2.a.ii, one of the required components of PCMH certification is integrated behavioral health and primary care. Therefore, the same components and potential impacts as for Project 3.a.i will apply for this project.

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 do not believe any 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, among other things:

- submission of an application by the PPS with the identification all providers involved in such model;
- the verification of the good standing of such providers by the Department, OMH and OASAS, as appropriate;
- satisfaction of the physical plant standards as delineated in Appendix A.

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

20.02 Refuah 2.a.i 10 NYCRR 710 10 NYCRR 715 10 NYCRR 754

Background and justification provided in your request: RCHC will establish an Article 28 birth center to be operated by one of its FQHC partners inside an Article 28 inpatient hospital. This co-location of services by two Article 28 providers would require Certificate of Need (CON) approval and compliance with certain physical plant requirements as a result of co-location. The requested regulatory relief would be for a waiver to exempt the birth center from undergoing the CON process, compliance with certain physical plant requirements associated with co-location of a birth center, or if applicable, an expedited review of the CON application. A key aspect of the Project 2.a.i Integrated Delivery System (IDS) is to ensure access to the full continuum of

care. Having a birth center will enable RCHC to fill a gap in the community and implement an effective—and cost effective—model of care aligned with community need and demand. Access to the birth center will be embedded into processes related to care management and coordination. It will also serve as a place for family-based care coordination and patient navigation.

CNA data revealed high birth rates in the service area and that maternal/child discharges (e.g., vaginal or cesarean deliveries, newborns with other problems) are among the top 20 Medicaid inpatient discharges in the service area. The creation of an Article 28 midwife-centered birth center located on the campus of one of RCHC's hospital partners will create an alternative to inpatient hospital deliveries. Midwife-centered birth centers, when compared to inpatient deliveries, can reduce costs, reduce cesarean deliveries and labor inductions, and promote patient-centered care for mother and child. A birth center is consistent with the IDS goal to reduce unnecessary hospital use, and a waiver from the requirements of 10 NYCRR 710, 715 and 754 would allow RCHC to include a birth center as part of its IDS.

Response to waiver request:

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

In cases where waivers are approved, the agencies will send letters directed to the providers which otherwise would be responsible for complying with the regulatory provisions at issue. Providers further will be advised that agency staff who conduct surveillance activities will be notified that these regulatory waivers have been approved; however, they should maintain a copy of their waiver letters at any site subject to surveillance.

Please note that the Department of Health will publish on its website a list of regulatory waivers that have been approved to assist PPSs in determining whether additional waivers may be appropriate for the activities within a PPS. Additional requests for waivers, as well as any questions regarding the foregoing, may be sent by email to DSRIP@health.ny.gov with Regulatory Waiver in the subject line.

Thank you for your cooperation with this initiative. We look forward to working with you to transform New York's delivery system.

Sincerely,

Howard Zucker M.D.

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

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

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

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.

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.

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

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.

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.

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.	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. 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.