February 20, 2015

Lutheran Medical Center
LUTHERAN MEDICAL CENTER
Claudia Caine, President and C.O.O.
150 55th Street
Brooklyn, New York 11220

Dear Ms. Caine:

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 Lutheran Medical Center in its capacity as lead for the Lutheran Medical 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 Lutheran Medical Center PPS Project Plan application are addressed below.

**32.01 Lutheran 3.a.i OMH: 14 §§ NYCRR 599.3(b), 599.4(r), (ab); OASAS: 14 NYCRR §§ 800.2(a)(6), (14), 810.3, 810.3(f), (l)**

Background and justification provided in your request: OMH regulations require Article 28 providers to obtain an OMH license if they provide more than 10,000 mental health visits annually, or if mental health visits comprise more than 30 percent of the provider’s annual visits and the total number of visits is at least 2,000 visits annually (the OMH threshold). OASAS regulations require an Article 28 provider to obtain a certification from OASAS if it provides any substance abuse services. Under 3.a.i, Article 28 providers will increase their provision of both mental health and substance abuse services so that patients can receive physical and behavioral health services in one setting. It is highly likely that some of the providers participating in 3.a.i will cross the OMH threshold, and all Article 28 providers that provide any substance abuse services would be required to obtain OASAS certification. Requiring OMH and/or OASAS licensure would impede the goals of 3.a.i and slow implementation of this project.

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 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.

**32.02 Lutheran ALL 10 § NYCRR § 600.9(c).**

Background and justification provided in your request: Section 600.9(c) prohibits a medical facility from sharing gross income or net revenue with an individual or entity that has not received establishment approval - This could be interpreted as prohibiting a hospital that receives DSRIP funds from distributing those funds to non-established providers, such as physician groups, who are in the same PPS. Such an interpretation would be contrary to one of the key elements of DSRIP: the distribution of funds by the lead coalition provider to other providers participating in the PPS.

Response to waiver request:

**Revenue Sharing. Approved.** The PPS requested a waiver of 10 NYCRR § 600.9, pertaining to revenue sharing. The waiver is approved to the extent that the regulation otherwise would prohibit providers from receiving DSRIP incentive payments distributed by the PPS Lead.
Background and justification provided in your request: Section 405.19(g) limits the number of observation beds to the lesser of 40 beds or 5 percent of a hospital’s capacity and requires observation units to be in a distinct physical space. Section 405.32(b)(1)(ii), a proposed new regulation which has a comment period that is set to expire on December 15, would eliminate Section 405.19(g) and would require hospitals to have policies to ensure that patients requiring observation care receive that care in “the proper clinical location.” Given the separate regulatory requirement that most hospitals have separate pediatric inpatient units, it is possible that Section 405.32(b)(1)(ii) could be interpreted to require the segregation of children and adults into distinct observation units. While the PPS’s project plan initially envisions an observation unit that only contains adults, eventually pediatric patients will be incorporated into the unit. The PPS seeks either an interpretation of the regulation that would allow children and adults to be treated in the same unit or a waiver of this particular regulatory provision.

Response to waiver request:

**Observation beds. No waiver needed.** The PPS requested waivers in connection with observation beds. No regulatory waiver is needed to increase its number of observation beds, nor is a waiver needed to allow both adult and pediatric patients to be treated in the same observation unit. However, the provider must have policies and procedures that ensure safety and appropriate pediatric-specific care to the pediatric child on a unit that normally treats adults. Alternatively, you may locate a pediatric observation patient in an inpatient pediatric bed.

32.04 Lutherann ALL 10 NYCRR § 405.9(f)(7)

Background and justification provided in your request: Section 405.9(f)(7) requires hospitals to ensure that patients may not be discharged or transferred to another location based upon source of payment. This regulation could be interpreted to prohibit hospitals from transferring their patients to other providers within the same PPS, since the hospital would have a financial relationship with the other provider. For example, if one hospital in a PPS were to transfer a patient to the lead coalition provider because the lead coalition provider specializes in treating the patient’s condition, this could be viewed as a transfer based on source of payment since the lead coalition provider distributes DSRIP funds to the transferring hospital.

Response to waiver request:

**Admission, Transfer and Discharge. No waiver needed.** The PPS requested waivers of 10 NYCRR § 405.9(f)(7), which provide important protections related to the admission, transfer or discharge of patients from in-patient settings, including prohibiting decisions about admission, transfer or discharge based on source of payment. No regulatory waiver is needed for purposes of permitting transfers and discharges of patients between PPS partners, provided that decisions to admit, transfer or discharge are clinically based and appropriate documentation is made thereof.

32.05 Lutheran 3.a.i 10 NYCRR §§ 401.2(b), 401.3(d)

Background and justification provided in your request: Section 401.2(b) allows the operating certificate of an Article 28 provider to be used only by the Article 28 operator at the Article 28 provider’s site of operation. The Department has interpreted this to mean that the operator must have exclusive site control and cannot share the site with another entity. Section 401.3(d) prohibits an Article 28 provider from leasing or subletting any portion of its facility
unless the entity that leases the facility conforms with all of the requirements imposed on Article 28 providers. In effect, these two provisions prohibit Article 28 providers from sharing space with any provider not licensed under Article 28—including a physician group practice, a clinic licensed by OMH, or a substance abuse clinic licensed by OASAS. This would prohibit Article 28 providers from allowing other providers with expertise in mental health care or substance abuse services to provide care in their facilities, thereby limiting their options at integrating care.

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 DSFIP Project 3.1.1 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;
- 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 DSFIP@health.ny.gov.

32.06 Lutheran 2.a.i, 2.b.iii, 2.b.ix, 3.a.i, 3.c.i 10 NYCRR §§ 670.1, 670.2, 670.3, 709.1, 709.2, 709.3, 710.1

Background and justification provided in your request: When Article 28 facilities seek to undertake certain projects, the certificate-of-need ("CON") regulations cited above require those facilities, including acute care facilities and residential care facilities, to submit applications to the Department, demonstrate a public need for their projects in the application, and obtain the Department prior approval before initiating their projects. The types of projects covered by the CON regulations include construction, renovation, and adding or deleting services. The projects listed above are likely to require providers to undertake construction and service changes that would implicate the CON rules. In particular: a) Project 2.a.i requires a large investment in primary care capacity and some providers will need to expand operations in order to meet that enhanced capacity; b) Project 2.a.i also requires investment health information technology infrastructure, and some HIT investments enacted by providers will fall within the scope of CON regulation; c) Project 2.b.ix (observation unit) will require construction and renovation at both a hospital and a nursing home (an outpatient unit will be moved to the nursing home as part of the project, and the nursing home will decertify beds in order to house the outpatient unit); d) Projects 2.b.iii (ED triage) and 3.a.i (behavioral health integration) will likely require the expansion of services at licensed providers, and may also require construction and renovation; and e) the plan for Project 3.c.i (diabetes) envisions the provision of new podiatry and vision services at certain Article 28 providers. Requiring a demonstration of public need and a separate application for these projects is unnecessary. Department approval of the DSFIP projects and their implementation plans should be sufficient, particularly in light of the fact that the PPS has conducted a community needs assessment, and used the results of that assessment to inform its project selection. The Department should waive the CON regulations for the projects listed above.

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:
  o No waiver is available for establishment applications.
  o 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.
  o 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.


Background and justification provided in your request: Sections 711.2 and 712-2.4 set construction standards for hospitals, and Subpart 713-4 sets construction standards for nursing homes. Section 710.9 requires a preopening survey after the completion of a construction project. As part of the observation unit project, an outpatient unit will be moved from Lutheran Medical Center to the Lutheran Augustana Center for Extended Care and Rehabilitation, a nursing home, to make room for the new observation unit, and therefore sections of both the medical center and the nursing home will undergo construction. The design of these new spaces may conflict with particular regulatory requirements for the design of hospitals and nursing homes. Such regulatory requirements incorporate provisions of the Guidelines for the Design and Construction of Health Care Facilities, which set out detailed rules for these facilities.

Response to waiver request:
  Construction Standards. Denied. The PPS requested waivers of §§ 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.

Pre-Opening Surveys. Denied. The PPS requested waivers of 10 NYCRR § 710.9, pertaining to CON pre-opening surveys. These requests are denied, as pre-opening surveys are an important patient safety protection. However, the Department will expedite pre-opening surveys connected with DSRIP projects to the extent possible.

32.08 Lutheran 2.b.iii, 2.b.ix, 3.a.i, 3.c.i, 3.d.ii 766.4(a), (b)

Background and justification provided in your request: Section 766.4 allows doctors, midwives, and nurse practitioners to order licensed home care services, but it does not allow
physician’s assistants (PAs) to order such care. As part of their efforts to keep patients out of the hospital, the DSRIP projects listed above are likely to involve orders for home care. For example, some patients who come to the emergency room or who obtain care in the PPS’s observation unit may be in need of personal care services back at home. Likewise, PPSs may provide home care to patients to help manage their diabetes and asthma care. Allowing PAs to order home care as part of these projects would enable these providers to order such care and thus could potentially play a role in reducing inpatient admissions.

Response to waiver request:
Determination Pending.

32.09 Lutheran 2.a.i, 2.b.iii, 2.b.ix, 2.c.i, 3.a.i, 3.c.i, 3.d.ii DOH: 10 NYCRR §§ 86-4.9(c)(8), 401.2(b); OMH: 14 NYCRR § 599.14; OASAS: 14 NYCRR § 822-3.1(b)

Background and justification provided in your request: Section 86-4.9(c)(8) prohibits freestanding ambulatory care facilities from billing for services provided off site. Section 401.2(b) allows an Article 28 to use its operating certificate only for services at its designated site of operation, which has been interpreted as prohibiting providers from providing services offsite. Sections 599.14 and 822-3.1(b) impose similar rules on mental health and substance abuse providers, respectively. Providers would benefit from the ability to provide services off site in carrying out multiple DSRIP projects. For example, nurses employed by Article 28 facilities may provide asthma care as part of the asthma home-based self-management program (3.d.ii) and social workers employed by Article 28 providers may seek to provide behavioral health services within a patient’s home (3.a.i). In short, providers seek the flexibility to provide needed care in the setting that is most conducive to treatment.

Response to waiver request:
Department- 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 DOH. In addition, DOH will explore, through Value-based Payment options, incorporating more flexibility for home visits, telemedicine and team visits.

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

OASAS- no waiver needed. OASAS is seeking to move from the clinic to the rehab State Plan Amendment which will permit off-site services.

32.10 Lutheran 3.a.i OMH: 14 NYCRR §§ 551.6, 551.7: OASAS: 14 NYCRR §§ 810.6, 810.7

Background and justification provided in your request: Section 551.6 requires Article 31 providers who are licensed by OMH to undergo prior approval review if they undertake certain projects, including the establishment of a new satellite location and the expansion of caseload by 25 percent or more for clinic treatment programs. Section 551.7 requires a demonstration of public need as part of this review. Similarly, Section 810.6 requires Article 32 providers who are
licensed by OASAS to undergo prior approval review if the provider offers services at a new location or increases capacity of a service where capacity is identified in the provider’s operating certificate, and Section 810.7 requires the applicant to demonstrate public need for its project as part of the review. Project 3.a.i is likely to fall within the reach of these regulations. As part of behavioral health integration, Article 31 and Article 32 providers are likely to provide services at new locations—more specifically, they may provide care within an Article 28 facility. While establishing a new satellite location is technically subject to “E-Z PAR” review, in practice this process is not easy for providers; they must obtain a letter of support from a local government unit, and the process can be lengthy. Requiring prior approval review for the behavioral health integration project would be duplicative of the DSRIP process itself, since the PPS will already have to submit its implementation plan to the state for review. There is no need to impose a separate prior approval review process on top of the review process embedded into DSRIP itself.

Response to waiver request:

Integrated services. Approved solely with respect 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 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.

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. 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.
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.
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), (f), (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)(3)(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 use 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

<table>
<thead>
<tr>
<th>Existing LICENSURE THRESHOLDS</th>
<th>DSRIP Project 3.a.i LICENSURE THRESHOLDS</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>A MHL Article 32 provider must be certified by OMH if more than 49 percent of its total annual visits are for mental health services.</td>
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