



Department
of Health

Office of
Mental Health

Office of Alcoholism and
Substance Abuse Services

March 13, 2015

Cathy Homkey, C.E.O.
Adirondack Health Institute
ADIRONDACK HEALTH INSTITUTE INC
9 Carey Road
Queensbury, New York 12804

Dear Ms. Homkey:

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 Adirondack Health Institute in its capacity as lead for the Adirondack Health Institute Performing Provider System (AHI 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 DSRIP 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 AHI PPS Project Plan application are addressed below.

23.01 AHI 2.a.i

Background and justification provided in your request:

(1) 2.a.i is implicated and it is a general concern regarding the PPS program. 2.a.i project requirements (9-10) are implicated because negotiating with private entities increases anti-trust risk.

(2) There are ongoing anti-trust concerns for the PPS. AHI requests that the proposed regulations be adopted so that COPA can be applied for. The waiver would facilitate implementation of an integrated system by providing certainty as to the activities that the PPS may undertake without state action.

(3) The PPS considered waiting for COPA, but due to the requirements of working with Medicaid MCOs, at the outset, the PPS felt the need for immediate clarity.

Response to waiver request:

COPA. Waiver not needed. COPA regulations were effective on December 17, 2014.

More information may be found at:

http://www.health.ny.gov/health_care/medicaid/redesign/copa/

23.02 AHI 2.a.i 10 NYCRR 405.1(c)

Background and justification provided in your request:

(1) The integrated delivery system of 2.a.i is generally implicated, but project requirement 10 is specifically implicated.

(2) The PPS requests a waiver because the PPS will adopt certain policies on behalf of PPS Partners and will make certain decisions regarding the provision of healthcare to patients in the PPS. The PPS should be specifically exempted from this requirement because its activities with PPS Partners will not rise to the level of operating Partner facilities. The requirement for establishment would be overly burdensome and will delay the timely formation of the PPS.

(3) The PPS considered requesting an expedited establishment review, but it was rejected because the activities of the PPS should be deemed to fall below the establishment threshold.

Response to waiver request:

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

23.03 AHI 2.a.i 10 NYCRR 600.9(c)

Background and justification provided in your request:

(1) 2.a.i is implicated and it is a general concern regarding the PPS program.

(2) The PPS and its Partners and Affiliates will receive certain distributions of funds pursuant to the DSRIP program that could be construed as fee splitting. The PPS requests a waiver of the requirement that an entity that splits fees needs to have establishment approval.

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.

23.04 AHI (1) 2.a.i. project requirements (4-7); 2.a.ii. Project requirements (4-6); 2.a.iv. Project requirements (4-6); 2.b.vii. Project requirement 10; 2.d.i. project requirement 17; 3.a.i. project requirement 4; 3.a.ii. Project requirement (2, 8, and 11); 3.a.iv. Project requirement 9; 3.g.i. project requirement 6; and 4.b.ii project requirement 4. Consent form.

Background and justification provided in your request:

(2) Without a regulation PPS Partners and Affiliates will be subject to lawsuits from patients regarding uses and disclosures of healthcare information. The PPS requests that a regulation be promulgated that allows the PPS to obtain a single consent for treatment, payment, and healthcare operations uses and disclosures to settle liability under New York law. The regulation could specifically cite the Department consent form being developed.

(3) The PPS could utilize the consent form that the Department is drafting; however, without the issue addressed in binding law there will be outstanding liability questions with regard to inter-PPS disclosures.

Response to waiver request:

Consent. No waiver needed. The PPS requested regulatory waivers to the extent available to permit the use of a common consent form across providers. No regulatory waiver is needed for this purpose. The agencies are collaborating on the development of a consent model that would facilitate the ability of PPS providers to appropriately coordinate care and will share that model in the near future.

23.05 AHI (1) All projects. 10 NYCRR 600.1; Parts 670; Parts 700

Background and justification provided in your request:

(2) The PPS requests that the Department, OMH, and OASAS create an integrated program for review of Public Need and Financial Feasibility for all PPS projects requiring CON or Prior Approval Review because requiring multiple agency review will make implementing the projects slower and more expensive.

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.

Review of this application will be a coordinated, integrated process between the Department, OASAS and OMH.

If a PPS later identifies the need for a waiver, a request can be made at that time.

23.06 AHI All projects.

Background and justification provided in your request:

The PPS requests that the Public Health and Health Planning Council schedule a bi-weekly videoconference meeting to accommodate required approvals emanating from approved PPSs. The PPS requests that the Behavioral Health Services Advisory Council schedule a monthly videoconference meeting to accommodate required approvals emanating from approved PPSs.

Response to waiver request:

Bi-weekly videoconferences to expedite approvals. Not applicable as a regulatory waiver was not requested. We will expedite all approvals associated with DSRIP projects. The suggestion will be taken into consideration.

23.07 AHI (1) 2.a.iv. project requirement 1. All projects involving bed and service relocations between Partners. 10 NYCRR 708.3(e); 10 NYCRR 708.4; 10 NYCRR 710.1(c)(4)(iv); 10 NYCRR 710.1(c)(5)(iv)

Background and justification provided in your request:

(2) The PPS requests an accelerated review requirement for bed and service relocations between PPS Partners. The bed and service relocations should only require letter notification to the Department and the review should be deemed to have occurred after 15 days. There is authority for this in 10 NYCRR 710.1(c)(4)(iv) which allows for certain changes to be made without an application and for limited review under 10 NYCRR 710.1(c)(5)(iv). The 180-day review period in 10 NYCRR 708.3(e) could be shortened to 15 days. This requires eliminating the specific 10 NYCRR 708.4(a) review criteria and substituting whether the relocations fit into the PPS's overall plan.

Response to waiver request:

Bed Capacity. Approved. The PPS requested waivers for regulations related to changes in bed capacity. 10 NYCRR §§ 710 and 401(e), pertaining to the CON process for changes in bed capacity, are approved provided that submission of information through NYSE-

CON is necessary for decreases in bed capacity and administrative review necessary for increases in bed capacity.

Department review deemed complete after 15 days. Denied. We will not deem Department review to have occurred after 15 days, however the Department will expedite all DSRIP projects.

23.08 AHI 10 NYCRR 401.3(g)

Background and justification provided in your request:

(1) If 2.a.i. is successful it will reduce the overall number of patients being admitted as inpatients. This may cause certain facilities or components of facilities to close.

(2) The PPS requests that the 90-day timeline for the Department to consider facility closure be reduced to 30 days to facilitate timely closures where it is necessary due to the PPS achieving its goals.

Response to waiver request:

Facility Closure. Denied. The PPS requested regulatory waivers in connection with the closure of a facility. While the Department will expedite approvals to the extent appropriate for facilitation of the PPS Project Plan, appropriate notice is important to patients/residents, families, vendors, other providers, and communities. Moreover, the Department cannot circumvent federal and state statutory requirements such as the federal Worker Adjustment and Retraining Notification (WARN) Act. The requests therefore are denied.

23.09 AHI 2.a.i. project requirements (4-7); 2.a.ii. Project requirements (4-6); 2.a.iv. Project requirements (4-6); 2.b.vii. Project requirement 10; 2.d.i. project requirement 19; 3.a.i. project requirement 4; 3.a.ii. Project requirement (2, 8, and 11); 3.a.iv. Project requirement 9; 3.g.i. project requirement 6; and 4.b.ii project requirement 4.10 NYCRR §§ 710.1(2), 710.1(3)(i)(q), 710.1(5)(iv)(g).

Background and justification provided in your request:

All of these project require use of HIT technologies and interoperability, this will require investment in new EHR technologies, capital and vendor services. The waiver is necessary so that the PPS and all partners do not need further review or approval from the Department regarding HIT acquisition, installation, modification or outlay of capital to implement necessary technology advances to participate in DSRIP project.

Response to waiver request:

HIT Standards. 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.

23.10 AHI

Background and justification provided in your request:

(1) All Projects dealing with integration of services will face scope of practice issues.

(2) The PPS requests that the Department exercise its authority to formally approve each PPS and its treating partners in order to become exempted from these scope of practice provisions for the professions of:

- Social Work (Education Law, Article 154),
- Psychology (Education Law, Article, 153),
- Mental Health Practitioners (Education Law, Article 163).

The authority for this is Section 9 of Chapter 420 of the Laws of 2002, as amended by chapter 132 of the laws of 2010, relating to the profession of social work; Subdivision a. of Section 17-a of chapter 676 of the laws of 2002, as amended by chapters 130 and 132 of the laws of 2010, and as further amended by chapter 57 of the laws of 2013, in relation to the profession of psychology and the four professions described as mental health practitioners.

The PPS also requests the extension of this scope of practice exemption beyond its July 1, 2016 sunset date.

Response to waiver request:

Scope of practice. Denied. We do not have the authority to waive State statute.

23.11 AHI All projects that plan to utilize the integrated outpatient services regulations. 10 NYCRR 600.2

Background and justification provided in your request:

The PPS requests in numerous locations that the Department adopt the proposed integrated outpatient services regulations so that the PPS can adopt those regulations. In the interim, the PPS requests that, for all projects where it has indicated a desire to utilize these regulations, the Department grant a waiver or approval under 10 NYCRR 600.2 to allow the PPS to begin the process of undertaking the selected projects in the interim in situations where primary care services will be provided at a facility licensed by OASAS or OMH.

Response to waiver request:

The integrated outpatient services regulations are now in effect, however we have also developed the following model as an alternative for providers under DSRIP:

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.

23.12 AHI 10 NYCRR 405.19 (g)

Background and justification provided in your request:
All projects that plan to utilize observation beds.

Response to waiver request:

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

23.13 AHI (2,5 (b)); 10 NYCRR 710.1(c)(2) or (3)

Background and justification provided in your request:

(2) The PPS requests a waiver to increase number of observation beds and a waiver physical space and location and Construction requirements for those beds regardless of cost. The PPS will comply with the applicable provisions of Parts 711 and 712-2 and section 712-2.4 of this Title for construction projects approved or completed after January 1, 2011.

Response to waiver request:

Bed Capacity. Approved. The PPS requested waivers of 10 NYCRR **710.1(c)(2)(3)**, pertaining to the CON process for changes in bed capacity. Regulations requiring that bed capacity increases be subject to a full CON review are waived. These requests are approved, provided that the facility submit a limited review application for decreases in bed capacity and an administrative review application for increases in bed capacity. The Department will expedite all applications related to DSRIP projects.

23.14 AHI 10 NYCRR 400.9 (c)(1) and (d).

Background and justification provided in your request:

(1) All projects that are impacted are the use of telemedicine to make decisions about transferring residents from SNFs when physicians, nurses and other clinical staff with the necessary training to make the transfer decision are not available.

(2) 10 NYCRR 400.9(c)(1) requires the personal, alternate or staff physician requests or agrees to the admission, transfer or discharge from a skilled nursing facility. The reasons for the waiver request is to allow transfer decisions to be evaluated in a timely way by health care professionals with the necessary expertise to facilitate transfers as needed, and avoid preventable transfers undertaken because of the unavailability of health care professionals at the SNF to evaluate the resident and make a transfer decision by utilizing tele-health and telemedicine services.

Response to waiver request:

Telehealth. No waiver needed. No waiver is needed however the facility should have policies and procedures that state the circumstances under which the personal, alternate or staff physician can provide such decision via telehealth.

23.15 AHI 10 NYCRR § 98-1.5(b)(6)(vii)

Background and justification provided in your request:

(1) 2.a.i. project requirement 8; 2.d.i. project requirements 6 and 10; 3.a.ii project requirement 3.

(2) The PPS will contract with Medicaid Managed Care Organizations as an integrated system and establish value based payment arrangements. This could require licensure as an IPA under 10 NYCRR 98-1.5(b)(6)(7). The PPS requests a waiver of the restriction on MCOs contracting with unlicensed entities for IPA services and recognize that the PPS may perform some IPA services. The PPS requests that it be exempt from the definition of an IPA under 10 NYCRR 98-1.2 (w).

Response to waiver request:

MCO contract for IPA services. Denied. In NYS, MCOs can only contract with providers and IPAs to arrange for the provision of services. At this time, MCOs contracting requirements and limitations cannot be waived. Legislation has been proposed to allow MCOs to contract directly with PPS entities without them becoming an IPA, however, many of the requirements of IPAs would be applicable and enforced.

23.16 AHI Public Health Law § 4901(9)(c)

Background and justification provided in your request:

(1) 2.a.i. project requirement 9.

(2) The PPS requests that regulations be promulgated indicating that the PPS is not a utilization review agent due to the Public Health Law § 4901(9)(c) exception. The Public Health Law provides that agents acting on behalf of the state and local government for services provided pursuant to title XIX of the federal social security act are not utilization review agents. The PPS will be analyzing utilization and medical necessity of various treatments, especially inpatient hospitalization, and could be deemed a utilization review agent.

Response to waiver request:

Utilization review agent. Denied. If the PPS is making medical necessity determinations such as authorizing and denying services, it is a UR agent and the Department cannot waive a statutory provision.

23.17 AHI Public Health Law § 18(6); Mental Hygiene Law § 33.13(c); Education Law § 6530(23); Article 32 Privacy.

Background and justification provided in your request:

(1) 2.a.i. project requirement 11; 2.d.i. project requirements 11 and 13; 4.a.iii project requirement 4 the PPS intends to share PPS data elements gathered from across the PPS with trainers in MEB health promotion.

(2) It would be a treatment purposes disclosure for the PPS to disclose information to healthcare providers within the PPS. However, it is not a treatment purposes disclosure to disclose information to engage patients in the integrated delivery system through outreach. As

such, the consent form the Department is currently drafting needs to be a HIPAA-compliant authorization for these activities. The consent form should only need to be obtained once to allow the PPS to conduct all activities required under the project plans. However, an authorization needs to be specific as to the entity to whom the information is to be released. Therefore, the Department will need to consult with CMS in drafting the authorization to determine if reference in the consent to an online list of PPS Partners and Affiliates will be sufficient for an authorization.

Response to waiver request:

Consent. No waiver needed. The PPS requested regulatory waivers to the extent available to permit the use of a common consent form across providers. No regulatory waiver is needed for this purpose. The agencies are collaborating on the development of a consent model that would facilitate the ability of PPS providers to appropriately coordinate care and will share that model in the near future.

23.18 AHI 10 NYCRR §§ 405.2(e)(3), 405.4(b)(4), 94(b)(2-3)

Background and justification provided in your request:

(1) 2.a.ii project requirement 8 dealing with behavioral health screening protocols.

(2) The PPS requests that providers be allowed to be credentialed at the PPS level. Effective PPS preventative care screening will require providers with appropriate credentials to be available in facilities that do not currently credential providers of that type. This will enable the creation of a single community wide practitioner base and waiver of these various state agency requirements. Administrative delays relating to multiple credentialing processes of the State and MCOs can impede a PPS's ability to provide access to care.

Response to waiver request:

Credentialing. Approved. The PPS requested waivers of 10 NYCRR § 405.2, for the purpose of allowing the PPS to gather and store credentialing information in a central repository and share such information with PPS providers as appropriate is approved. There must be a process in place for each provider in the PPS. Each individual practitioner must be privileged by each facility.

94(b)(2-3). More information is needed as to what regulation you are seeking to waive.

23.19 AHI 10 NYCRR §§ 400.11(a) and 700.3(a)(1-2); 700.3(c).

Background and justification provided in your request:

(1) 2.a.ii project requirement 8 dealing with behavioral health screening protocols.

(2) The PPS requests that the requirements of specific screening tools and specific staff training be waived to allow PPS providers to use alternate screening assessment tools approved by the PPS and to permit staff with alternate training to complete such assessments.

Response to waiver request:

PRI requirement. Approvable on a case-by-case basis. 10 NYCRR 400.11(a) requires Hospital/Community PRI or PRI as well as the SCREEN. We will waive the PRI

requirement in 400.11(a) on a case-by-case basis provided that the provider notify, and obtain approval from, the department for an alternative screening tool.

SCREEN requirement. Denied. We cannot waive the SCREEN portion of this regulation or the credentialing requirements for the person who completes the SCREEN, as this is a federal requirement.

23.20 AHI 10 NYCRR § 710.1(c)(1-5,7) - add or change method of service

Background and justification provided in your request:

(1) 2.a.iv project requirement 1.

(2) The PPS requests a waiver of the requirements of department approval of changes to the extent and kind of services to be provided at PPS Partner Article 28 facilities. The PPS requests a waiver of the factors for determining public need and the specific review process. The PPS requests a waiver of the requirement determination of public need and prior review and approval. The PPS requests that such approval be deemed granted upon review and approval of this application and any supplemental filings regarding specific projects. This is necessary in order to convert outdated and unneeded hospital infrastructure and programs into other types of hospital based programs within a medical village. The process of applying for Department approval would be time-consuming, especially given the number of requests within the next several years.

Response to waiver request:

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

- No waiver is available for establishment applications.
- Only the public need and financial feasibility components of the CON process are waived, meaning that a construction application still needs to be filed through NYSE-CON and provider compliance will still be reviewed.
- No waiver is available for specialized services, CHHA service area expansions, and hospital and NH bed increases, which will be determined on a case-by-case basis.

23.21 AHI 10 NYCRR §§ 401.3(e), 670.1 (a-b), 710.1(c)(1)(v). - add or reduce bed capacity

Background and justification provided in your request:

(1) 2.a.iv project requirement 1.

(2) The PPS requests waiver of need for new CON and need methodology for determination of public need and prior review and approval of decreases in bed capacity. The PPS proposes that approval of the DSRIP Project application be deemed approval of any bed reduction contained therein. However, the PPS requests that if prior review is required only that the Department only require letter notification going forward.

Response to waiver request:

Bed Capacity. Approved. The PPS requested waivers of 10 NYCRR §§ 710 and 401(e), pertaining to the CON process for changes in bed capacity. These requests are approved, provided that submission of information through NYSE-CON is necessary for decreases in bed capacity and administrative review necessary for increases in bed capacity. The Department will expedite all applications related to DSRIP projects.

23.22 AHI 10 NYCRR 401.3(g) - reduce or eliminate a service

Background and justification provided in your request:

(1) 2.a.iv project requirement 1.

(2) The PPS requests that the Department reduce the notice period of 401.3(g) from 90 to 30 days. The reduced period will address the need to rapidly change and reconfigure services. This is necessary to allow changes to healthcare delivery in a timely fashion due to the high volume of such requests throughout the state.

Response to waiver request:

Facility Closure. Denied. The PPS requested regulatory waivers in connection with the closure of a facility. While the Department will expedite approvals to the extent appropriate for facilitation of the PPS Project Plan, appropriate notice is important to patients/residents, families, vendors, other providers, and communities. Moreover, the Department cannot circumvent federal and state statutory requirements such as the federal Worker Adjustment and Retraining Notification (WARN) Act. The requests therefore are denied.

23.23 AHI 10 NYCRR 405.9 (f)(3)(ii)

Background and justification provided in your request:

(1) 2.b.viii project requirement 1.

(2) The PPS requests a waiver of hospital-specific review criteria for post-hospital discharge planning needs and to permit PPS created rapid response teams to conduct the discharge review analysis for the facility. This is necessary because otherwise the Hospital will be required to have a duplicative service or review of decisions. This will permit PPS-approved policies to be utilized and permit PPS rapid response teams to implement those policies.

Response to waiver request:

Hospital-specific review criteria for post-hospital discharge. Denied. The PPS requests a waiver of 405.9(f)(3)(ii), which requires that the hospital utilize written criteria for discharge based upon the hospital's experience with patients requiring post-hospital discharge. This proposal entails the PPS performing functions described in 10 NYCRR § 405.1(c), it will require establishment as set forth in § 405.1(c).

23.24 AHI 10 NYCRR 761.2 (b), 760.4, and 760.5.

Background and justification provided in your request:

(1) 2.b.viii project requirement 1.

(2) The PPS requests a waiver allowing an automatic amendment to the operating certificate of any Home Health Agency within the PPS changing the service area, required under 10 NYCRR 761.2 (b), to include the entire PPS geographic area. Specifically, the PPS would like to expand the geographic service area to include additional areas located within the PPS area as needed based on the CAN analysis for accomplishing DSRIP objective without showing public need and methodology.

Response to waiver request:

Expansion of CHHA service area. Determination pending.

23.25 AHI 18 NYCRR 505.20(b)(3); 18 NYCRR 540.5.

Background and justification provided in your request:

(1) 2.b.viii project requirement 1.

(2) The PPS requests a waiver of the requirement that the hospital have staff members responsible for discharge planning and arranging alternate care. The PPS requests that the Rapid Response Team be allowed to perform this function for the hospital. The PPS requests that this satisfy the requirements for the Hospital to obtain prior authorization under 18 NYCRR 540.5.

Response to waiver request:

Rapid response team perform discharge planning for hospital. More information needed. OASAS seeks additional information clarifying the proposal including if this is this a hospital detox program. Please provide such information to Trishia Allen of OASAS via email at Trishia.Allen@oasas.ny.gov.

23.26 AHI 14 NYCRR 36.4(a)(1)

Background and justification provided in your request:

(1) 2.b.viii project requirement 1.

(2) The PPS requests a waiver of the requirement that the hospital have staff members responsible for discharge planning and arranging alternate care. The PPS requests that the Rapid Response Team be allowed to perform this function for the hospital.

Response to waiver request:

Rapid response team perform discharge planning. Denied. The regulation cited does not actually require that facility staff perform this function. Rather, it requires that the facility, in cooperation with the local department of social services and community mental hygiene, take all necessary steps to obtain an adequate supply of housing for patients to be discharged or conditionally released. The requirement that staff perform the discharge planning function is statutory, set forth in MHL Section 29.15, and we do not have the authority to waive statute.

23.27 AHI 10 NYCRR 766.4(b)

Background and justification provided in your request:

(1) 2.b.viii project requirement 2; 3.a.ii project requirement ii.

(2) The PPS requests that a waiver be granted expanding the ability of R.N.s, N.P.s, and P.A.s to write orders for admission and discharge of treatment in the home care setting. This is necessary because the PPS will be expanding the use of home care and the rate of necessary orders may outpace M.D. capacity.

Response to waiver request:

Orders in home care setting-LHCSA. Determination pending.

23.28 AHI 10 NYCRR 763.7(a)(3)

Background and justification provided in your request:

(1) 2.b.viii project requirement 2

(2) The PPS requests that a waiver be granted expanding the ability of N.P.s and P.A.s to write orders for treatment in the home care setting. The PPS requests that the requirement of signature be waived so that electronic review by an authorized practitioner can be utilized. The PPS also requests that the N.P.s and P.A.s be treated as authorized practitioners regardless of supervision or countersignature by an M.D. This is necessary for PPS activities because the PPS will be expanding the use of home care faster than the rate at which M.D.s can supervise and write orders.

Response to waiver request:

Orders in home care setting- CHHAs. Denied. CHHAs must meet the federal conditions of participation, which requires that a physician sign medical orders. We do not have the authority to waive federal regulations.

23.29 AHI 10 NYCRR 405.9 (b)(2)

Background and justification provided in your request:

(1) 2.b.viii project requirement 3

(2) The PPS requests that a waiver be granted to allow the protocol to be applied to Medicaid patients only. Otherwise a literal reading of the regulation would lead to a situation where a patient could claim that he or she was denied admission into the hospital due to source of payment.

Response to waiver request:

Admission, Transfer and Discharge. Denied. 10 NYCRR § 405.9(b)(2) provides 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.

23.30 AHI 10 NYCRR 405.9 (f)(7)

Background and justification provided in your request:

(1) 2.b.viii project requirement 3

(2) The PPS requests that a waiver be granted to allow the PPS to allow it and its providers to only apply its protocol to Medicaid patients and, thus, include source of payment as one of the factors considered in the decision to discharge to home care.

Response to waiver request:

Admission, Transfer and Discharge. Denied. 10 NYCRR § 405.9 provides 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.

23.31 AHI 10 NYCRR 405.9(a)

Background and justification provided in your request:

(1) 2.b.viii project requirement 3

(2) The PPS requests a waiver of this regulation because it requires a transfer agreement. The PPS feels that the PPS clinical protocol could take the place of a transfer agreement in many situations because local health care providers, including hospitals and skilled nursing facilities will have signed on to the protocol.

Response to waiver request:

Transfer and affiliation agreements. No waiver needed. The PPS requested a waiver of 10 NYCRR § 405.9(a) regarding establishing and implementing written admission and discharge policies. No waiver is needed as no additional transfer and affiliation agreements are needed provided the PPS has already established such policies among the partners within the PPS. Such agreements must meet the requirements listed in 10 NYCRR § 405.9.

23.32 AHI 14 NYCRR 504.5

Background and justification provided in your request:

(1) 2.b.viii project requirement 3

(2) The PPS requests a waiver of this regulation so that it can develop a protocol that includes appropriate placement of patients leaving transitional care. This is necessary because this protocol is too inflexible for behavioral health services in an integrated delivery system.

Response to waiver request:

More information is required. It is unclear which provisions of this regulation are being sought for waiver and why the waiver would facilitate this transition. The regulations are protective of individual rights; therefore, before granting any waiver related thereto, OMH believes a much clearer showing of what is being sought to waive, why such a waiver would facilitate transition (for the client, not the program), and what alternative mechanism of ensuring client rights is proposed. Please email Keith McCarthy of OMH with such information at Keith.McCarthy@omh.ny.gov.

23.33 AHI 8 NYCRR 63.10(b)(2)

Background and justification provided in your request:

(1) 2.b.viii project requirement 7.

(2) The PPS requests a waiver of this regulation so that a facility can be affiliated with a pharmacist through the PPS and a pharmacist can be credentialed for medication management as part of PPS wide credentialing. The regulation currently poses an impediment to this because it has strict requirements for clinical experience and facility affiliation.

Response to waiver request:

Requirements for pharmacist medication management. Denied. We do not have the authority to wave State Education Law or regulations.

23.34 AHI

Background and justification provided in your request:

The PPS requests that the Department finalize the proposed telehealth and telemedicine regulations.

Response to waiver request:

Telehealth regulations. Waiver not needed. We are not aware of the need for regulations to allow telehealth services to be performed. A bill is pending that will allow for payment of telemedicine services. Should the bill become law, regulations will be adopted in this regard.

23.35 AHI 10 NYCRR 401.3 (a)(1-3) and 710.1 (b) (c)(1-5, 7)

Background and justification provided in your request:

(1) 2.a.iv project requirement 1 for each Medical Village; 3.a.i. - North Star Behavioral Health (NSBHS) integration with Malone Health Center primary care, Adirondack Health's new Lake Placid Health and Wellness Center, Nathan Littauer hospital co-location with Family Counseling Center, Behavioral Health Services North (BHSN) and HHHN in Plattsburgh and Center for Well-Being in Morrisonville; 3.a.iv - Plattsburgh project; 4.a.iii project requirement 2.

(2) The PPS requests that the Department grant a waiver of the requirement for determinations of public need and prior review and approval for construction projects contained in the DSRIP Project application. To the extent review is deemed necessary, the PPS requests that the Department only require limited review or architectural review only.

Response to waiver request:

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

- No waiver is available for establishment applications.
- Only the public need and financial feasibility components of the CON process are waived, meaning that a construction application still needs to be filed through NYSE-CON and provider compliance will still be reviewed.
- No waiver is available for specialized services, CHHA service area expansions, and hospital and NH bed increases, which will be determined on a case-by-case basis.

Construction Standards. Denied. The PPS requested waivers of §§ 401.3, which sets 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.

23.36 AHI 10 NYCRR §§ 710.7(b-c) 710.7 (d)

Background and justification provided in your request:

(1) 2.a.iv project requirement 1 for each Medical Village; 3.a.i. - North Star Behavioral Health (NSBHS) integration with Malone Health Center primary care, Adirondack Health's new Lake Placid Health and Wellness Center, Nathan Littauer Hospital co-location with Family Counseling Center, Behavioral Health Services North (BHSN) and HHHN in Plattsburgh and Center for Well-Being in Morrisonville; 3.a.iv - Plattsburgh project; 4.a.iii project requirement 2.

(2) The PPS requests that a waiver of the requirement that the Department advise the PPS in writing that it can commence construction under 10 NYCRR 710.7 (d) and instead deem the submission under section 710.7(b-c) of the regulations complete after 15 days. This is necessary to ensure the ability to rapidly commence construction and renovation projects within the three-year implementation period for DSRIP.

Response to waiver request:

Approval to start construction. Approvable on a case- by-case basis. 10NYCRR 710.7(a) states that the applicant may seek approval to start construction of the project, or one or more phases thereof, upon the filing with the department completed contract documents consistent with all previous approvals. The Department will review such requests on a case-by-case basis and will expedite the review of all DSRIP projects.

23.37 AHI 10 NYCRR 710.9

Background and justification provided in your request:

(1) 2.a.iv project requirement 1 for each Medical Village; 3.a.i. - Franklin County: North Star Behavioral Health (NSBHS) integration with Malone Health Center primary care, Essex County: Adirondack Health (AH) is developing a new Lake Placid Health and Wellness Center, Nathan Littauer Hospital will co-locate BH with Family Counseling Center (FCC), Clinton County: Behavioral Health Services North (BHSN) and HHHN, Behavioral Health Services North (BHSN) and HHHN will partner to bring PCPs into the Center for Wellbeing (CWB); 3.a.iv Plattsburgh project; 4.a.iii project requirement 2.

(2) The PPS requests that the Department expedite the pre-opening inspection and survey to within 15 days, and allow the facility to remain open while non-patient areas are under review. This is necessary to ensure the ability to rapidly begin operation once renovation and building projects are complete.

Response to waiver request:

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.

23.38 AHI 10 NYCRR 703.6

Background and justification provided in your request:

(1)3.a.i. - North Star Behavioral Health (NSBHS) integration with Malone Health Center primary care, Adirondack Health's new Lake Placid Health and Wellness Center, Nathan Littauer hospital co-location with Family Counseling Center, Behavioral Health Services North (BHSN) and HHHN in Plattsburgh and Center for Well-Being in Morrisonville; 3.a.iv - Plattsburgh project; 4.a.iii project requirement 2.

(2) The PPS requests that the Department treat extension clinics and diagnostic and treatment centers as part-time clinics under 10 NYCRR 710.6 for purposes of review the construction and operating standards for each project. The waiver is necessary to aid the PPS during the transition phase.

Response to waiver request:

Review of construction and operating standards for D and TCs. Approvable on a case- by- case basis. The Department will review such requests on a case-by-case basis and will expedite the review of all DSRIP projects.

23.39 AHI

Background and justification provided in your request:

The PPS requests that the Department petition CMS to allow the Department to waive CMS co-location requirements when it is deemed in the best interests of promoting the objectives of DSRIP.

Response to waiver request:

Petition CMS to change their requirements. Not applicable as regulatory waiver not requested. This request will be taken into advisement.

23.40 AHI 14 NYCRR 599.4(r)

Background and justification provided in your request:

(1) 3.a.i the Franklin County: North Star Behavioral Health (NSBHS) integration with Malone Health Center primary care; 4.a.iii project requirement 2.

(2) The PPS will not utilize the proposed integrated service provider regulations because this will be a true, shared space project and the Malone Health Center primary care will not be an established operator responsible for patient care by North Star Behavioral Health. The PPS requests a waiver of the requirement, under 14 NYCRR 599.4(r), increasing the number of mental health visits that a diagnostic and treatment center can conducting before it is required to be licensed. Instead, the PPS requests a more flexible approach that looks at the primary purpose for the facility.

Response to waiver request:

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

Model outlined in Appendix A to this letter. The Department, OMH and OASAS have determined that no additional waivers are needed if providers are integrating services under such model. As noted in Appendix A, the use of this model is contingent upon:

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

If a PPS later identifies the need for a waiver, a request can be made at that time.

23.41 AHI 10 NYCRR 401.1(g); 10 NYCRR § 710.1(c)(3)

Background and justification provided in your request:

(1) The North Star Behavioral Health (NSBHS) integration with Malone Health Center primary care is an established provider that is moving its facility to a more central location; 4.a.iii project requirement 2.

(2) The new extension clinic would generally be subject to administrative review under 10 NYCRR § 710.1(c)(3) and 401.1(g) the PPS requests that upon approval of this application the administrative review process be waived and the PPS be authorized to submit construction plans.

Response to waiver request:

Review of new extension clinic. Approvable on a case-by-case basis. The department will review such requests on a case-by-case basis and will expedite the review of all DSRIP projects.

23.42 AHI

Background and justification provided in your request:

(1) 3.a.i Essex County: Adirondack Health (AH) is developing a new Lake Placid Health and Wellness Center; 4.a.iii project requirement 2.

(2) The PPS will utilize the proposed integrated services provider regulations and apply to add mental health services at a new extension clinic. The PPS requests that those regulations be finalized as soon as possible. The PPS requests that approval of this application be deemed concurrent approval of the integrated services center application under 14 NYCRR § 599-1.15(f). In the alternative, the PPS requests that any multiple agency reviews be consolidated into a single review process to expedite the authorization for 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 a PPS later identifies the need for a waiver, a request can be made at that time.

23.43 AHI 10 NYCRR § 710.1(c)(3)

Background and justification provided in your request:

(1) 3.a.i Essex County: Adirondack Health (AH) is developing a new Lake Placid Health and Wellness Center; 4.a.iii project requirement 2.

(2) The new extension clinic would generally be subject to administrative review under 10 NYCRR § 710.1(c)(3) and 401.1(g) the PPS requests that upon approval of this application the administrative review process be waived and the PPS be authorized to submit construction plans.

Response to waiver request:

Review of new extension clinic. Approvable on a case- by- case basis. The department will review such requests on a case-by-case basis and will expedite the review of all DSRIP projects.

23.44 AHI 14 NYCRR 599.4(r)

Background and justification provided in your request:

1) 3.a.i the Franklin County: North Star Behavioral Health (NSBHS) integration with Malone Health Center primary care; 4.a.iii project requirement 2.

(2) The PPS will not utilize the proposed integrated service provider regulations because this will be a true, shared space project and the Malone Health Center primary care will not be responsible for patient care by Clinton County Mental Health and Addiction Services. The PPS requests a waiver of the requirement, under 14 NYCRR 599.4(r), increasing the number of mental health visits that a diagnostic and treatment center or extension clinic can conduct before OMH licensure is required for that space.

Response to waiver request:

Integrated services. Approved solely with respect to 14 NYCRR 599.4(r) and (ab), which will be waived contingent upon following the DSRIP Project 3.a.i Licensure Threshold Model outlined in Appendix A to this letter. The Department, OMH and OASAS have determined that no additional waivers are needed if providers are integrating services under such model. As noted in Appendix A, the use of this model is contingent upon:

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

If a PPS later identifies the need for a waiver, a request can be made at that time.

23.45 AHI 10 NYCRR 401.3 (d)

Background and justification provided in your request:

(1) 3.a.i the Franklin County: North Star Behavioral Health (NSBHS) integration with Malone Health Center primary care; 4.a.iii project requirement 2.

(2) The PPS requests a waiver of 10 NYCRR 401.3 (d) to permit the lease of Article 28 approved space to North Star Behavioral Health (NSBHS) without meeting the requirements of 10 NYCRR 401.1. This is necessary because otherwise it could be deemed necessary for Malone Health Center to obtain an operating certificate over the treatment provided by NSBHS. This would unnecessarily delay the timely commencement of operations at Malone Health Center.

Response to waiver request:

Integrated services. Approved solely with respect to 14 NYCRR 599.4(r) and (ab), which will be waived contingent upon following the DSRIP Project 3.a.i Licensure Threshold Model outlined in Appendix A to this letter. The Department, OMH and OASAS have determined that no additional waivers are needed if providers are integrating services under such model. As noted in Appendix A, the use of this model is contingent upon:

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

If a PPS later identifies the need for a waiver, a request can be made at that time.

23.46 AHI 14 NYCRR § 599-1

Background and justification provided in your request:

(1) 3.a.i. - Hudson Headwaters Health Network will integrate services at all of its 15 primary care sites, expending on the existing pilot it has had success with at the main Queensbury primary care clinic. Four of these sites will receive behavioral health services via tele-medicine; 4.a.iii project requirement 2.

(2) The PPS intends to utilize the proposed integrated outpatient services center regulations once those regulations are promulgated. The PPS requests that those regulations be finalized as soon as possible. The PPS requests that approval of this application be deemed concurrent approval of the integrated services center application under 14 NYCRR § 599-1.15(f). In the alternative, the PPS requests that any multiple agency reviews be consolidated into a single review process to expedite the authorization for 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 a PPS later identifies the need for a waiver, a request can be made at that time.

OMH-More information needed. OMH supports any telepsychiatry services to be provided, pursuant to the standards of 14 NYCRR 599.17. The PPS should further explain what it seeks to do, re-examine the regulations to be found at Section 599.17, and specify what particular provisions may be preventing them from proceeding with their desired project. Please e-mail Keith McCarthy of OMH with such information at Keith.McCarthy@omh.ny.gov.

23.47 AHI 14 NYCRR 599.4(r)

Background and justification provided in your request:

(1) 3.a.i. – Four Hudson Headwaters Health Network sites will receive behavioral health services via tele-medicine; 4.a.iii project requirement 2.

(2) The PPS intends to utilize the proposed tele-psychiatry regulations once those regulations are promulgated. The PPS requests that those regulations be finalized as soon as possible. The PPS requests a waiver of the 2000 visit per year requirement for these lower-volume HHHN sites that are using telemedicine services. Providing regulatory certainty on this issue will allow HHHN to proceed with attempting to increase volume of behavioral health care provided without concern for the number of visits per year.

Response to waiver request:

Integrated services. Approved solely with respect to 14 NYCRR 599.4(r) and (ab), which will be waived contingent upon following the DSRIP Project 3.a.i Licensure Threshold Model outlined in Appendix A to this letter. The Department, OMH and OASAS have determined that no additional waivers are needed if providers are integrating services under such model. As noted in Appendix A, the use of this model is contingent upon:

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

If a PPS later identifies the need for a waiver, a request can be made at that time.

23.48 AHI 14 NYCRR § 599-1

Background and justification provided in your request:

(1) 3.a.i. - Glens Falls Hospital (GFH) will integrate behavioral health into four hub PCP practices; 4.a.iii project requirement 2.

(2) The PPS intends to utilize the proposed integrated outpatient services center regulations once those regulations are promulgated. The PPS requests that those regulations be finalized as soon as possible. The PPS requests that approval of this application be deemed concurrent approval of the integrated services center application under 14 NYCRR § 599-1.15(f). In the alternative, the PPS requests that any multiple agency reviews be consolidated into a single review process to expedite the authorization for this project.

Response to waiver request:

More information needed. If the hub PCP practices in reference are not licensed as an Article 28, please provide us with more detailed information and we will make a determination on a case-by-case basis.

If the hub PCP practices in reference are licensed as an Article 28:

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.

23.49 AHI 14 NYCRR 599.4(r)

Background and justification provided in your request:

(1) Nathan Littauer Hospital will co-locate BH services at three of its primary care centers (Gloversville, Decker, and Perth). Family Counseling Center (FCC) will provide BH services; 4.a.iii project requirement 2.

2) The PPS will not utilize the proposed integrated service provider regulations because this will be a true shared space project and the Nathan Littauer Hospital will not be responsible for patient care by Family Counseling Center. The PPS requests a waiver of the requirement, under 14 NYCRR 599.4(r), increasing the number of mental health visits that a diagnostic and treatment center or extension clinic can conduct before OMH licensure is required for that space.

Response to waiver request:

More information needed. If the primary care centers in reference are not licensed as an Article 28, please provide us with more detailed information and we will make a determination on a case-by-case basis.

If the primary care centers in reference are licensed as an Article 28:

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.

23.50 AHI 10 NYCRR 401.3 (d)

Background and justification provided in your request:

(1) 3.a.i. Nathan Littauer Hospital will co-locate BH services at three of its primary care centers (Gloversville, Decker, and Perth). Family Counseling Center (FCC) will provide BH services; 4.a.iii project requirement 2.

(2) The PPS requests a waiver of 10 NYCRR 401.3 (d) to permit the lease of Article 28 approved space to Family Counseling Center without meeting the requirements of 10 NYCRR 401.1. This is necessary because otherwise it could be deemed necessary for Nathan Littauer Hospital to obtain an operating certificate over the treatment provided by FCC. This would unnecessarily delay the timely commencement of operations at Nathan Littauer Hospital.

Response to waiver request:

More information needed. If the primary care centers in reference are not licensed as an Article 28, please provide us with more detailed information and we will make a determination on a case-by-case basis.

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.

23.51 AHI 10 NYCRR 401.2 (b)

Background and justification provided in your request:

(1) 3.a.i HHHN will provide primary care services to patients at BHSN's center for wellbeing.

(2) The PPS requests a waiver of the limitation that an operating certificate only permits activities on one site and requests that HHHN, a licensed Article 28 FQHC, be allowed to send primary care physicians to BHSN's site. This is necessary in order to ensure the smooth integration of primary care physicians working in Article 28 hospitals and extension clinics into the Behavioral Health context.

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.

23.52 AHI 3.a.i 14 NYCRR 587.4 (7)

Background and justification provided in your request:

(1) 3.a.i HHHN will provide primary care services to patients at BHSN's center for wellbeing.

(2) 14 NYCRR 587.4 (7) defines a provider of service as an entity that is responsible for operation of a program. The remainder of that part imposes certain requirements on providers of services for the operation of outpatient programs. The PPS requests a waiver of the definition of a provider of service to exclude primary care practices, like HHHN, from complying with the requirements of that subpart applicable to providers of services when co-located with a bona-fide provider of services.

Response to waiver request:

More information needed. OMH seeks additional information clarifying the proposal such as if the "primary care practices" will be licensed by the Department under Article 28. Please provide such information to Keith McCarthy of OMH via e-mail at Keith.McCarthy@omh.ny.gov.

23.53 AHI 3.a.i 14 NYCRR 587.20 (a)

Background and justification provided in your request:

(1) 3.a.i HHHN will provide primary care services to patients at BHSN's center for wellbeing.

(2) There is a requirement that there be psychiatric coverage in any outpatient program. 14 NYCRR 587.20(a) contains an ability to waive this requirement when there is no psychiatrist available, there is an appropriately trained physician, and there is a showing of need. The PPS requests an expansion of the waiver allowing physician coverage solely on the basis of a showing of need as presented in the Project Application. This is necessary in order to enlarge the scope of services at the facility and to allow limited mental health treatment by the providers

of the primary care practice. In addition, it is needed regionally due to the shortage of psychiatrists.

Response to waiver request:

More information needed. OMH seeks additional information clarifying the proposal such as if physical and behavioral health services will be integrated into an Article 28-licensed clinic setting. The applicant appears to seek a waiver of the requirement that out-patient programs have psychiatrist coverage, yet merely states that they wish to “enlarge the scope of services at the facility and to allow limited mental health treatment by the providers of the primary care practice.” Depending upon the model being pursued, OMH might wish to see that there exists a formalized arrangement with a psychiatrist for consultation/coverage. The IMPACT (“collaborative care”) model certainly requires such a relationship. OMH needs to better understand what is being proposed. Please provide such information to Keith McCarthy of OMH via e-mail at Keith.McCarthy@omh.ny.gov.

23.54 AHI 10 NYCRR 401.2 (b)

Background and justification provided in your request:

(1) 3.a.i GFH will provide primary care services to patients at its own behavioral health clinics.

(2) The PPS requests a waiver of the limitation that an operating certificate only permit activities on one site and requests that GFH, a licensed Article 28 hospital, be allowed to send primary care physicians to its behavioral health clinics to perform primary care services. This is necessary in order to aid the smooth integration of primary care physicians working in Article 28 hospitals and extension clinics into the Behavioral Health context.

Response to waiver request:

Off-Site Services or Home Visits. Approved. The PPS requested waivers of 10 NYCRR § 401.2(b) for the purpose of allowing practitioners affiliated with Article 28 providers to provide services outside of the certified service site. The request is approved, contingent upon notification by the PPS of the specific providers, practitioners and services. However, reimbursement for the provision of such services would not be available absent approval of a State Plan Amendment (SPA) to the State Medicaid Plan and associated state regulations, both of which are being pursued by the Department. The Department will explore, through Value-based Payment options, incorporating more flexibility for home visits, telemedicine and team visits.

23.55 AHI 14 NYCRR § 599-1

Background and justification provided in your request:

(1) 3.a.i. - Glens Falls Hospital (GFH) will integrate primary care into its behavioral health clinics.

(2) The PPS intends to utilize the proposed integrated out-patient services center regulations once those regulations are promulgated. The PPS requests that those regulations be finalized as soon as possible. The PPS requests that approval of this application be deemed concurrent approval of the integrated services center application under 14 NYCRR § 599-

1.15(f). In the alternative, the PPS requests that any multiple agency reviews be consolidated into a single review process to expedite the authorization for 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 a PPS later identifies the need for a waiver, a request can be made at that time

In addition, please note that the Integrated Out-patient Services regulations are now in effect, should the Licensure Threshold Model, outlined in Appendix A to this letter, not meet your needs.

23.56 AHI 14 NYCRR 587.20 (a)

Background and justification provided in your request:

(1) 3.a.i GFH will provide primary care services to patients at its own behavioral health clinics.

(2) There is a requirement that there be psychiatric coverage in any out-patient program. 14 NYCRR 587.20(a) contains an ability to waive this requirement when there is no psychiatrist available, there is an appropriately trained physician, and there is a showing of need. The PPS requests an expansion of this waiver allowing physician coverage solely on the basis of a showing of need, as presented in the Project Application. This is necessary in order to enlarge the scope of services at the facility and to allow limited mental health treatment by the providers of the primary care practice. In addition, it is needed regionally due to the shortage of psychiatrists.

Response to waiver request:

More information needed. OMH seeks additional information clarifying the proposal such as if physical and behavioral health services will be integrated into an Article 28-licensed clinic setting. The applicant appears to seek a waiver of the requirement that outpatient programs have psychiatrist coverage, yet merely states that they wish to “enlarge the scope of services at the facility and to allow limited mental health treatment by the providers of the primary care practice.” Depending upon the model being pursued, OMH might wish to see that there exists a formalized arrangement with a psychiatrist for consultation/coverage. The IMPACT (“collaborative care”) model certainly requires such a relationship. OMH needs to better understand what is being proposed. Please provide such information to Keith McCarthy of OMH via e-mail at Keith.McCarthy@omh.ny.gov.

23.57 AHI 14 NYCRR § 599-1

Background and justification provided in your request:

(1) 3.a.i. - Community, Work & Independence (CWI), Inc. will integrate PCPs into its Foothills behavioral health clinics.

(2) The PPS intends to utilize the proposed integrated outpatient services center regulations once those regulations are promulgated. The PPS requests that those regulations be finalized as soon as possible. The PPS requests that approval of this application be deemed concurrent approval of the integrated services center application under 14 NYCRR § 599-1.15(f). In the alternative, the PPS requests that any multiple agency reviews be consolidated into a single review process to expedite the authorization for 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 a PPS later identifies the need for a waiver, a request can be made at that time.

In addition, please note that the Integrated Out-patient Services regulations are now in effect, should the Licensure Threshold Model outlined in Appendix A to this letter not meet your needs.

23.58 AHI 14 NYCRR 587.20 (a)

Background and justification provided in your request:

(1) 3.a.i CWI will provide primary care services to patients at its own behavioral health clinics.

(2) There is a requirement that there be psychiatric coverage in any outpatient program. 14 NYCRR 587.20(a) contains an ability to waive this requirement when there is no psychiatrist available, there is an appropriately trained physician, and there is a showing of need. The PPS requests an expansion of this waiver allowing physician coverage solely on the basis of a showing of need, as presented in the Project Application. This is necessary in order to enlarge the scope of services at the facility and to allow limited mental health treatment by the providers of the primary care practice. In addition, it is needed regionally due to the shortage of psychiatrists.

Response to waiver request:

More information needed. OMH seeks additional information clarifying the proposal such as if physical and behavioral health services will be integrated into an Article 28-licensed clinic setting. The applicant appears to seek a waiver of the requirement that outpatient

programs have psychiatrist coverage, yet merely states that they wish to “enlarge the scope of services at the facility and to allow limited mental health treatment by the providers of the primary care practice.” Depending upon the model being pursued, OMH might wish to see that there exist a formalized arrangement with a psychiatrist for consultation/coverage. The IMPACT (“collaborative care”) model certainly requires such a relationship. OMH needs to better understand what is being proposed. Please provide such information to Keith McCarthy of OMH via e-mail at Keith.McCarthy@omh.ny.gov.

23.59 AHI 10 NYCRR 405.9 (b)(2)

Background and justification provided in your request:

The regulation requested for waiver is 10 NYCRR 405.9 (b)(2). The Projects requested for: 2.b.iv; 2.b.vii; and 3.a.ii to permit providers to implement PPS-approved protocols for care transitions and care pathways, protocols to manage patients in appropriate settings and implement project goals to reduce E.D. and in-patient hospital usage.

Response to waiver request:

Admission, Transfer and Discharge. No waiver needed. The PPS requested waivers to regulations 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.

23.60 AHI 10 NYCRR 405.9 (f)(7)

Background and justification provided in your request:

2.b.iv; 2.b.vii; and 3.a.ii. The regulation requested for waiver is 10 NYCRR 405.9 (f) (7) to permit providers to implement PPS-approved protocols for care transitions and care pathways, protocols to manage patients in appropriate settings and implement project goals to discharge patients to the appropriate post-acute setting.

Response to waiver request:

Admission, Transfer and Discharge. 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.

23.61 AHI 10 NYCRR 405.9 (f)(3)(ii)

Background and justification provided in your request:

The regulation requested for waiver is 10 NYCRR 405.9 (f) (7). The Projects requested for: 2.b.iv to permit providers to implement PPS-approved protocols for care transitions and care pathways, protocols to manage patients in appropriate settings and implement project goals to discharge patients to the appropriate post-acute setting.

Response to waiver request:

Admission, Transfer and Discharge. 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.

23.62 AHI 14 NYCRR 589.5(h)

Background and justification provided in your request:

(1) 3.a.iv project requirement 1 - Citizen Advocates (CAI) and North Star Behavioral Health Services (NSBHS) will run an ambulatory detox facility at the Malone Outpatient Clinic Center and also a satellite ambulatory detox at the Malone Crisis Stabilization Center. All other integrated providers of ancillary outpatient detox services are also impacted by this regulation and as such the PPS requests a general waiver of this regulation.

(2) 14 NYCRR 822-3.1(11)(h) provides that programs may not bill for any other service categories while a patient is admitted to the out-patient rehabilitation service. This means that if a patient is already admitted or enrolled with an OASAS out-patient provider, then a satellite facility providing ancillary detox services is unable, per the billing regulations, to bill for services. So, for example, if a patient is in the Malone Out-patient Program with St. Joseph's Rehab, and comes to/or is referred to the Crisis Stabilization Center in Malone for ancillary detox, the Crisis Stabilization Center would be unable to admit the patient to this separate out-patient satellite program. Given that the goal of the PPS is to expand access to such out-patient services to avoid in-patient treatment episodes, the PPS requests that these regulations be waived.

Response to waiver request:

Approvable on a case-by-case basis. Federal rules prohibit duplication of services. OASAS would be willing to waive regulations that necessitate the duplication of services. Citizen Advocates must designate reporting protocols to ensure continuation of net deficit financing and compliance with federal reporting requirements. The provider must submit ambulatory detox protocols to OASAS Medical Director for approval. Please provide such information to Trishia Allen of OASAS via email at Trishia.Allen@oasas.ny.gov.

23.63 AHI 14 NYCRR § 599-1

Background and justification provided in your request:

(1) - Mental Health Association in Essex County will expand its existing one mobile crisis worker and one respite bed in Elizabethtown to add additional mobile crisis workers and 4 short-term crisis respite/ambulatory detox beds.

(2) The PPS intends to utilize the proposed integrated out-patient services center regulations once those regulations are promulgated. The PPS requests that those regulations be finalized as soon as possible. The PPS requests that approval of this application be deemed concurrent approval of the integrated services center application under 14 NYCRR § 599-1.15(f). In the alternative, the PPS requests that any multiple agency reviews be consolidated

into a single review process to expedite the authorization for this project. The use of the regulations is necessary to allow OASAS and OMH services to be provided in the same location.

Response to waiver request:

More information needed. In the event that this proposal was approved, it would be contingent upon the PPS's submission of detox protocols to the OASAS Medical Director for review and approval.

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.

In addition, please note that the Integrated Out-patient Services regulations are now in effect, should the Licensure Threshold Model outlined in Appendix A to this letter not meet your needs.

23.64 AHI 14 NYCRR §§ 589.5(h)(6)(i-ii)

Background and justification provided in your request:

(1) Mental Health Association in Essex County will expand its existing one mobile crisis worker and one respite bed in Elizabethtown to add additional mobile crisis workers and 4 short-term crisis respite/ambulatory detox beds.

(2) The PPS requests a waiver of the requirements to seek prior approval from OMH for major changes in the program and physical location of a crisis stabilization program. This is necessary in order to expeditiously commence the increase in services at the Essex county site.

Response to waiver request:

Crisis stabilization program. More information needed. OASAS seeks clarification from the PPS on why existing provider capacity for the region was not used. In the event that this proposal was approved, it would be contingent upon the PPS's submission of detox protocols to the OASAS Medical Director for review and approval. Please provide such information to Trishia Allen of OASAS via email at Trishia.Allen@oasas.ny.gov.

23.65 AHI 10 NYCRR 401.3 (d)

Background and justification provided in your request:

(1) Citizen Advocates Inc. (CAI), North Star Behavioral Health (NSBH) will establish a full service 24-hour Crisis Stabilization Center (CSC) in the former Alice Hyde Hospital Nursing Home, 1st floor.

(2) Currently, the PPS believes that the property is still owned by Alice Hyde Hospital. As such, Alice Hyde will be leasing space to a provider with an OMH license. The PPS requests a waiver of 10 NYCRR 401.3(d) permitting the lease of its Article 28 space without meeting requirements of 10 NYCRR 401.1 et. seq.

Response to waiver request:

Integrated services. Approved solely with respect to 14 NYCRR 599.4(r) and (ab), which will be waived contingent upon following the DSRIP Project 3.a.i Licensure Threshold Model outlined in Appendix A to this letter. The Department, OMH and OASAS have determined that no additional waivers are needed if providers are integrating services under such model. As noted in Appendix A, the use of this model is contingent upon:

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

If a PPS later identifies the need for a waiver, a request can be made at that time.

23.66 AHI 14 NYCRR 551.6 (c)(1)(i)

Background and justification provided in your request:

(1) Citizen Advocates Inc. (CAI), North Star Behavioral Health (NSBH) will establish a full service 24-hour Crisis Stabilization Center (CSC) in the former Alice Hyde Hospital Nursing Home, 1st floor.

(2) 14 NYCRR 551.6 (c)(1)(i) requires Prior Approval review of new projects for established providers in new locations. The PPS requests a waiver for prior approval review of this project upon approval of this Project Application.

Response to waiver request:

PAR. Public Need and Financial Feasibility. Approved. The public need and financial feasibility components of the PAR process are waived, however an application still needs to be filed and provider compliance will still be reviewed.

23.67 AHI 14 NYCRR § 599-1

Background and justification provided in your request:

(1) 3.a.ii. - Mental Health Association in Essex County will expand its existing one mobile crisis worker and one respite bed in Elizabethtown to add additional mobile crisis workers and 4 short-term crisis respite/ambulatory detox beds.

(2) This project will be collocated in a hospital, but it will also provide a mix of crisis stabilization services and withdrawal management services. The PPS intends to utilize the proposed integrated outpatient services center regulations once those regulations are

promulgated. The PPS requests that those regulations be finalized as soon as possible. The PPS requests that approval of this project application be deemed concurrent approval of the integrated services center application under 14 NYCRR § 599-1.15(f). In the alternative, the PPS requests that any multiple agency reviews be consolidated into a single review process to expedite the authorization for this project. The use of the regulations is necessary to allow the OASAS and OMH services to be provided in the same location.

Response to waiver request:

Integrated services. Approved solely with respect to 14 NYCRR 599.4(r) and (ab), which will be waived contingent upon following the DSRIP Project 3.a.i Licensure Threshold Model outlined in Appendix A to this letter. The Department, OMH and OASAS have determined that no additional waivers are needed if providers are integrating services under such model. As noted in Appendix A, the use of this model is contingent upon:

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

If a PPS later identifies the need for a waiver, a request can be made at that time.

In addition, please note that the Integrated Out-patient Services regulations are now in effect, should the Licensure Threshold Model outlined in Appendix A to this letter not meet your needs.

23.68 AHI 14 NYCRR 551.6 (c)(1)(i)

Background and justification provided in your request:

(1) 3.a.ii. - crisis stabilization beds will be developed and housed at Glens Falls Hospital.

(2) Glens Falls Hospital is currently licensed by OMH with both out-patient clinics and in-patient beds. 14 NYCRR 551.6 (c)(1)(i) requires Prior Approval review of new projects for established providers. The PPS requests a waiver for prior approval review of this project upon approval of this Project Application. The PPS requests this regulation to accelerate the process of implementing this project.

Response to waiver request:

PAR. Public Need and Financial Feasibility. Approved. The public need and financial feasibility components of the PAR process are waived, however an application still needs to be filed and provider compliance will still be reviewed.

23.69 AHI 14 NYCRR 590.3; 14 NYCRR 590.4;

Background and justification provided in your request:

(1) 3.a.ii project requirement 9.

(2) The PPS is going to establish a central triage service with agreements among participating psychiatrists, mental health, behavioral health, and substance abuse providers.

Currently, a hospital authorized under 9.39 is the only entity authorized to establish admission and discharge triage criteria as a Comprehensive Psychiatric Emergency Program.

The PPS requests a waiver of this provision allowing the PPS Partners to develop joint protocols for admission and discharge of psychiatric patients in a similar manner as a 9.39 hospital in a Comprehensive Psychiatric Emergency Program.

Response to waiver request:

Central triage service. More information needed. OMH seeks additional information clarifying the proposal that waiving Section 590.3 would mean that none of the provisions of the CPEP regulations would apply to the provider, while waiving Section 590.4 would likewise mean that none of the definitions would apply, if waiving Section 590.3, none of the provisions of Part 590 would have any bearing regardless. OMH needs to better understand what is being proposed. Please e-mail Keith McCarthy of OMH with such information at Keith.McCarthy@omh.ny.gov

Central triage service. More information needed. OASAS requests that medical protocols be submitted to the OASAS Medical Director for review and approval. Please e-mail Trishia Allen of OASAS at Trishia.Allen@oasas.ny.gov

23.70 AHI 14 NYCRR 810, 814, 814.7, 816, 822-2, 822-4

Background and justification provided in your request:

Developing detox services including ambulatory detox, short-term respite beds for detox patients, and an outpatient SUD site with integrated PCP team. Additional respite beds will be developed to serve crisis stabilization patients through project 3.a.ii—with overlap between patients, co-location will be beneficial to share costs and staff. This is a new facility and will require capital costs to repurpose, 7 RNs (3 shifts, 24/7), 7 certified recovery coaches (some part-time), 3 Credentialed Alcoholism & Substance Abuse Counselors (CASAC), 1 Social Worker, 0.5 medical director, 1 NP, and 4 admin/food service staff. The program will also need transportation services, appropriate referral protocols from local E.D.s, as well as linkages to in-patient services. The partners have identified an existing facility in Schuylers Falls that will be re-purposed.

Response to waiver request:

More information needed. OASAS seeks additional information clarifying where the proposed project will take place. Also, please clarify if withdrawal and stabilization protocols have already been submitted to OASAS Medical Director for approval or if these services are new for the provider. Please provide such information to Trishia Allen of OASAS via e-mail at Trishia.Allen@oasas.ny.gov.

23.71 AHI Detox 14 NYCRR 810.6(a)(1)

Background and justification provided in your request:

(1) 3.a.iv project requirement 1 - BHSN will be creating an ambulatory detoxification clinic next to its OMH clinic in Morrisonville New York.

(2) 14 NYCRR 810.6(a)(1) allows for administrative review of all applications for certification of certified services. An ambulatory detox facility is a certified service. The PPS

requests a waiver of the requirement of administrative review and requests that certification be granted for this certified service based on this project application.

Response to waiver request:

Administrative review of detox clinic. Denied. OASAS would consider an application for co-location or integration within the OMH clinic but cannot waive requirements for a location that is outside of and next to the existing OMH clinic. OASAS seeks clarification from PPS on why existing provider capacity for the region was not used. Please provide such information to Trishia Allen of OASAS via e-mail at Trishia.Allen@oasas.ny.gov.

23.72 AHI 14 NYCRR 814.7

Background and justification provided in your request:

(1) 3.a.iv project requirement 1 - BHSN will be creating an ambulatory detoxification clinic next to its OMH clinic in Morrisonville New York.

(2) The PPS requests a waiver of the shared space requirements under 14 NYCRR 814.7. Putting two facilities in the same vicinity is beneficial because it will enable sharing of costs and staff. Moreover, the detox facility will utilize the services of primary care teams. Thus, to accomplish the goals of integration, the PPS requests that these regulations be waived for this project. The PPS also requests that OASAS petition CMS to allow it to further waive certain federal shared space requirements.

Response to waiver request:

More information needed. OASAS seeks clarification from PPS on why existing provider capacity for the region was not used. Additionally, the ambulatory detox protocols must be submitted to the OASAS Medical Director for approval. Federal requirements cannot be waived. Please provide such information to Trishia Allen of OASAS via e-mail at Trishia.Allen@oasas.ny.gov.

23.73 AHI 14 NYCRR 800.2(a)(3) and 810.3

Background and justification provided in your request:

1) 3.a.iv project requirement 1 - BHSN will be creating an ambulatory detoxification clinic next to its OMH clinic in Morrisonville New York.

(2) The clinic will utilize the services of primary care teams. 14 NYCRR 822-2 provides that Chemical Dependence Out-patient and Opioid Treatment Programs are chemical dependence services. The PPS requests a waiver of the definition of provider of chemical dependence services 800.2(a)(3) and 810.3 as it applies to primary care teams practicing in this co-located facility. There is authority for this under 800.3(a)

Response to waiver request:

Approvable on a case-by-case basis. Please clarify if the services to be provided will be chemical dependence withdrawal and stabilization services, or out-patient chemical dependence treatment services. If approved, the provider must submit ambulatory detox protocols to OASAS Medical Director for approval. Please provide such information to Trishia Allen of OASAS via e-mail at Trishia.Allen@oasas.ny.gov.

23.74 AHI 14 NYCRR 810.6(a)(1)

Background and justification provided in your request:

(1) 3.a.iv project requirement 1 - by Citizen Advocates (CAI) and North Star Behavioral Health Services (NSBHS) will run an ambulatory detox facility at the Malone Out-patient Clinic Center.

(2) 14 NYCRR 810.6(a)(1) allows for administrative review of all applications for certification of certified services. An ambulatory detox facility is a certified service. The PPS requests a waiver of the requirement of administrative review and requests that certification be granted for this certified service based on this project application.

Response to waiver request:

Approvable on a case-by-case basis. The provider must submit ambulatory detox protocols to OASAS Medical Director for approval. Please provide such information to Trishia Allen of OASAS via e-mail at Trishia.Allen@oasas.ny.gov.

23.75 AHI 14 NYCRR 810.5(a)(1)

Background and justification provided in your request:

(1) 3.a.iv project requirement 1 - the Malone Out-patient Clinic Center will house ambulatory detox services run by Citizen Advocates (CAI) and North Star Behavioral Health Services (NSBHS).

(2) 14 NYCRR 810.5 requires full establishment for a provider that will establish any service where that provider has not been previously certified by OASAS to provide substance use disorder services. As Malone Out-patient Clinic Center will likely be a diagnostic and treatment center, it will need to have an OASAS establishment to comply with 10 NYCRR 401.3 (d). As such, the PPS requests a waiver of these regulations as to the housing of this project by Malone Out-patient Clinic Center.

Response to waiver request:

Approvable on a case-by-case basis. The provider must submit ambulatory detox protocols to OASAS Medical Director for approval. Please provide such information to Trishia Allen of OASAS via e-mail at Trishia.Allen@oasas.ny.gov.

23.76 AHI 14 NYCRR 800.2(a)(3) and 810.3

Background and justification provided in your request:

(1) 3.a.iv project requirement 1 - by Citizen Advocates (CAI) and North Star Behavioral Health Services (NSBHS) will run an ambulatory detox facility at the Malone Out-patient Clinic Center

(2) The clinic will utilize the services of primary care teams. 14 NYCRR 822-2 provides that Chemical Dependence Out-patient and Opioid Treatment Programs are chemical dependence services. The PPS requests a waiver of the definition of provider of chemical dependence services (800.2(a)(3) and 810.3), as it applies to primary care teams practicing in this co-located facility. There is authority for this under 800.3(a)

Response to waiver request:

Integrated services. Approved solely with respect to 14 NYCRR 599.4(r) and (ab), which will be waived contingent upon following the DSRIP Project 3.a.i Licensure Threshold Model outlined in Appendix A to this letter. The Department, OMH and OASAS have determined that no additional waivers are needed if providers are integrating services under such model. As noted in Appendix A, the use of this model is contingent upon:

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

If a PPS later identifies the need for a waiver, a request can be made at that time.

23.77 AHI 14 NYCRR 814.7

Background and justification provided in your request:

(1) 3.a.iv project requirement 1 - Citizen Advocates (CAI) and North Star Behavioral Health Services (NSBHS) will run an ambulatory detox facility at the Malone Out-patient Clinic Center.

(2) The PPS requests a waiver of the shared space requirements under 14 NYCRR 814.7. Co-locating these services with out-patient services is beneficial because it will enable sharing of costs and staff. Moreover, the detox facility will utilize the services of primary care practitioners. Thus, to accomplish the goals of integration the PPS requests that these regulations be waived for this project. The PPS also requests that OASAS petition CMS to allow it to further waive certain federal shared space requirements.

Response to waiver request:

Ambulatory detox facility. Approvable on a case-by-case basis. OASAS is not familiar with the federal requirement that would prohibit this project. The provider is already authorized to do Integrated Licensure, provided that the PPS submits detox protocols to the OASAS Medical Director for approval. Please provide such information to Trishia Allen of OASAS via e-mail at Trishia.Allen@oasas.ny.gov.

23.78 AHI 14 NYCRR 810.6; 14 NYCRR 810.13 (c)(2)

Background and justification provided in your request:

(1) 3.a.iv project requirement 1 - Citizen Advocates (CAI) and North Star Behavioral Health Services (NSBHS) will run an ambulatory detox facility at the Malone Out-patient Clinic Center and also a satellite ambulatory detox at the Malone Crisis Stabilization Center.

(2) Because Citizen Advocates (CAI) and North Star Behavioral Health Services (NSBHS) will already have been established as an operator by OASAS an additional site of operation will only require administrative review under 14 NYCRR 810.6. The PPS requests that this be waived, pursuant to the approval of this Project Plan. Similarly 14 NYCRR 810.13 (c)(2) allows satellite facilities, but requires that the operator be located within one county. The

PPS requests that this requirement be waived for this project and for the entire PPS to allow greater ability to create satellite programs.

Response to waiver request:

Ambulatory detox facility. Approvable on a case-by-case basis. OASAS seeks clarification from PPS on if SUD services are already currently being provided at this location. Please provide such information to Trishia Allen of OASAS via e-mail at Trishia.Allen@oasas.ny.gov.

23.79 AHI 10 NYCRR §§ 401.3(e), 670.1 (a-b), 710.1(c)(1)(v).

Background and justification provided in your request:

(1) 3.a.iv project requirement 1 – reduction in inpatient beds at the Adirondack Health Medical Village and the establishment of 5 inpatient beds by St. Joseph’s Rehab and Treatment Center.

(2) The PPS requests waiver of the requirement for a new CON and need methodology for determination of public need and prior review and approval of decreases in bed capacity. Currently, Adirondack Health plans to reduce its inpatient bed capacity by five for in-patient detox beds. The PPS proposes that approval of the DSRIP Project application be deemed concurrent approval of any bed reduction contained therein. However, the PPS requests that if prior review is required that the Department only require limited review going forward.

Response to waiver request:

Bed Capacity. Approved. The PPS requested waivers of 10 NYCRR 401.3 and 710.1, pertaining to the CON process for changes in bed capacity. Regulations requiring that bed capacity increases be subject to a full CON review are waived. These requests are approved, provided that the facility submit a limited review application for decreases in bed capacity and an administrative review application for increases in bed capacity. The Department will expedite all applications related to DSRIP projects.

23.80 AHI 10 NYCRR 401.3 (d)

Background and justification provided in your request:

(1) 3.a.iv project requirement 1 – reduction in inpatient beds at the Adirondack Health Medical Village and the establishment of five in-patient beds by St. Joseph’s Rehab and Treatment Center.

(2) The space where St. Joseph’s Rehab and Treatment Center will run the out-patient beds is within property that will be otherwise licensed as an Article 28. As such, Adirondack Health will be leasing space to a non- Department-licensed provider. The PPS requests a waiver of 10 NYCRR 401.3(d) permitting the lease of its Article 28 space without meeting requirements of 10 NYCRR 401.1 et. seq.

Response to waiver request:

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

determined that no additional waivers are needed if providers are integrating services under such model. As noted in Appendix A, the use of this model is contingent upon:

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

If a PPS later identifies the need for a waiver, a request can be made at that time.

23.81 AHI 14 NYCRR 810.6(a)(1); 14 NYCRR 810.13 (c)(2)

Background and justification provided in your request:

(1) 3.a.iv project requirement 1 – reduction in inpatient beds at the Adirondack Health Medical Village and the establishment of five in-patient beds by St. Joseph’s Rehab and Treatment Center.

(2) Because St. Joseph’s Rehab and Treatment Center already is an established operator by OASAS an additional site of operation will only require administrative review under 14 NYCRR 810.6. The PPS requests that this be waived, pursuant to the approval of the Project Plan. Similarly 14 NYCRR 810.13 (c)(2) allows satellite facilities, but requires that the operator be located within one county. The PPS requests that this requirement be waived for this project and for the entire PPS to allow greater ability to create satellite programs.

Response to waiver request:

Change in OASAS-licensed beds. More information needed. OASAS requests additional information specifying what level of care St. Joseph’s would be operating. Please provide such information to Trishia Allen of OASAS via e-mail at Trishia.Allen@oasas.ny.gov.

23.82 AHI 14 NYCRR 810.5

Background and justification provided in your request:

(1) 3.a.iv project requirement 1 – reduction in inpatient beds at the Adirondack Health Medical Village and the establishment of five in-patient beds by St. Joseph’s Rehab and Treatment Center.

(2) 14 NYCRR 810.5 regulation requires full establishment for a provider that will establish any service where that provider that has not been previously certified by OASAS to provide substance use disorder services. As Adirondack Health is an Article 28 hospital, it will need to have an OASAS establishment to comply with 10 NYCRR 401.3 (d). As such, the PPS requests a waiver of 14 NYCRR 810.5 as to the housing of this project at Adirondack Health.

Response to waiver request:

Change in OASAS-licensed beds. More information needed. OASAS requests additional information as this proposal conflicts with proposal 23.81. It appears the proposal is to have two OASAS providers offering the same service in the same building. Please provide such information to Trishia Allen of OASAS via e-mail at Trishia.Allen@oasas.ny.gov.

23.83 AHI 14 NYCRR 822-5.13(c)

Background and justification provided in your request:

(1) 3.a.iv project requirement 4.

(2) The PPS requests that a waiver be applied to all providers identified and linked with the PPS to provide opioid medical maintenance of the requirements from portions of Part 822 pertaining to counseling, and record-keeping requirements. This is provided for in 14 NYCRR 822-5.13(c), but the PPS requests that the waiver be applied as a matter of course, or that bulk notifications to OASAS be deemed sufficient.

Response to waiver request:

OASAS counseling and recordkeeping requirements. More information needed. OASAS requests clarification from the PPS regarding “all providers identified and linked with the PPS to provide opioid medical maintenance”. Please define if this is “all PPS providers” or “all MAT providers identified in the PPS.” Further, OASAS is only aware of one MAT provider within this PPS; this provider has been operational for only one year. OMM requires that a patient have been in an OTP, and successful, for four years. Please clarify if the provider currently has a methadone program. The use of methadone or suboxone for treatment purposes requires both state and federal approval. State approval will not be waived and federal requirements cannot be waived. Please provide such information to Trishia Allen of OASAS via e-mail at Trishia.Allen@oasas.ny.gov.

23.84 AHI 14 NYCRR 822-5.13(b)

Background and justification provided in your request:

(1) 3.a.iv project requirement 4.

(2) The PPS requests that a waiver be allowed for the specific requirements of this section pertaining to minimum OMM criteria. This will allow the program to be further expanded where it is appropriate.

Response to waiver request:

OASAS OMM criteria. More information needed. OASAS requests clarification from the PPS regarding if the provider currently has a methadone program. The use of methadone or suboxone for treatment purposes requires both state and federal approval. State approval will not be waived.

23.85 AHI 14 NYCRR 816.5(c)

Background and justification provided in your request:

(1) 3.a.iv project requirement 5.

(2) 14 NYCRR 816.5(c) contains requirements applicable to all chemical dependence withdrawal and stabilization services and specifically requires that there are certain policies and procedures that must be adopted by the governing body. The PPS requests a waiver of this requirement for programs under the PPS allowing those programs to adopt the PPS withdrawal management protocols without the need to have the governing body adopt the protocols. The governing body could instead adopt the PPS program by resolution.

Response to waiver request:

Chemical dependence withdrawal services. Approvable on a case-by-case basis.
The PPS needs to provide notification to OASAS that the PPS intends to incorporate any withdrawal protocols. Please provide such information to Trishia Allen of OASAS via e-mail at Trishia.Allen@oasas.ny.gov.

23.86 AHI 14 NYCRR 800.2(a)(3) and 810.3

Background and justification provided in your request:

(1) 3.a.iv project requirement 5

(2) The community-based withdrawal management and detoxification protocols may be utilized by primary care physicians that either have a presence in out-patient programs as part of a primary care team or are simply part of the PPS that have a high volume of patients that could benefit from use of the protocol. The PPS requests a waiver from 14 NYCRR 800.2(a)(3) and 810.3 to make clear that such primary care physicians would not be deemed Opioid Treatment Programs.

Response to waiver request:

Integrated services. Approved solely with respect to 14 NYCRR 599.4(r) and (ab), which will be waived contingent upon following the DSRIP Project 3.a.i Licensure Threshold Model outlined in Appendix A to this letter. The Department, OMH and OASAS have determined that no additional waivers are needed if providers are integrating services under such model. As noted in Appendix A, the use of this model is contingent upon:

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

If a PPS later identifies the need for a waiver, a request can be made at that time.

23.87 AHI 10 NYCRR Part 790.16 (a-e); 10 NYCRR 792.1(c)

Background and justification provided in your request:

(1) 3.g.i. project requirement 2.

(2) 10 NYCRR Part 790.16(a-e) mandates that there must be a determination of public need for hospice programs. This need methodology should be eliminated to facilitate PPS-wide coverage. Similarly, the requirement to list a specific service area under 10 NYCRR 792.1(c) should be waived for each hospice service working with the PPS to allow PPS-wide service.

Response to waiver request:

Public need for hospice. Determination pending.

23.88 AHI 14 NYCRR 822-3.1(11)(h)

Background and justification provided in your request:

1) 3.a.iv all projects. Specifically, Citizen Advocates (CAI) and North Star Behavioral Health Services (NSBHS) will run an ambulatory detox facility at the Malone Out-patient Clinic Center and also a satellite ambulatory detox at the Malone Crisis Stabilization Center. All other integrated providers of ancillary out-patient detox services are also impacted by this regulation and as such the PPS requests a general waiver of this regulation.

(2) 14 NYCRR 822-3.1(11)(h) provides that programs may not bill for any other service categories while a patient is admitted to the out-patient rehabilitation service. This means that if a patient is already admitted or enrolled in an OASAS out-patient provider, then a satellite facility providing ancillary detox services is unable, per the billing regulations, to bill for services. So, for example, if a patient is in the Malone Out-patient Program with St. Joseph's Rehab, and comes to/or is referred to the Crisis Stabilization Center in Malone for ancillary detox, the Crisis Stabilization Center would be unable to admit the patient to this separate outpatient satellite program. Given that the goal of the PPS is to expand access to such out-patient services to avoid in-patient treatment episodes, the PPS requests that these regulations be waived.

Response to waiver request:

OASAS detox services- Approvable on a case-by-case basis provided Citizen Associates designates reporting protocols to ensure continuation of net deficit financing and compliance with Federal reporting requirements. The provider must submit ambulatory detox protocols to OASAS Medical Director for approval. Please provide such information to Trishia Allen of OASAS via e-mail at Trishia.Allen@oasas.ny.gov.

23.89 AHI 14 NYCRR 599.14(f); 14 NYCRR 588.5(e)

Background and justification provided in your request:

(1) 3.a.i and 3.a.iv all projects. Specifically, patients receiving outpatient treatment for mental health services at other providers or locations may be referred for treatment at the Crisis Stabilization Center. All other integrated providers of out-patient mental health services are also impacted by this regulation and, as such, the PPS requests a general waiver of this regulation.

(2) 14 NYCRR 599.14(f) provides that a clinic may not be reimbursed for services provided to an individual currently enrolled in another licensed mental health out-patient program for which Medicaid reimbursement is being made, unless certain exceptions apply. 14 NYCRR 588.5(e) provides that, upon admission to a specific out-patient program, reimbursement shall be made for participation in that program only, unless certain exceptions apply. It further specifies that in no event shall a recipient be concurrently admitted to a clinic treatment program, a continuing day treatment program and an intensive psychiatric rehabilitation treatment program. The PPS requests that this provision be waived to allow admission in multiple out-patient clinics or under multiple programs so that a patient's care can be spread across those clinics, according to PPS-approved protocols. This is critical to the goal of reducing in-patient psychiatric hospitalization, because it will allow patients to receive care in the most convenient location, as consistent with PPS protocols and the level of care available.

Response to waiver request:

OMH-More information needed. While OMH can envision scenarios where this request could be supportable, not enough information is provided to allow for a proper response. Need to know more about the settings/programs potentially involved. Please e-mail Keith McCarthy of OMH with such information at Keith.McCarthy@omh.ny.gov.

23.90 AHI Education Law §§ 6512, 6513, 6509(9), 6509-a.

Background and justification provided in your request:

(1) 2.a.i. and all projects dealing with creating an integrated delivery system.

(2) The PPS requests that a regulation be promulgated clarifying that the activities of a PPS would not constitute the practice of medicine. In particular, the PPS requests clarification that the creation of a single system of credentialing within the PPS does not constitute the corporate practice of medicine.

Response to waiver request:

Corporate Practice of Medicine. Denied. The PPS requested regulatory waivers in connection with the corporate practice of medicine, which is a statutory doctrine and therefore cannot be waived. This request is therefore denied. Please note, however, that the provision of health care services by an Accountable Care Organization (ACO) shall not be considered the practice of a profession under Education Law Title 8, and a PPS may submit an application for an ACO certificate of authority. See 10 NYCRR § 1003.14(f); http://www.health.ny.gov/health_care/medicaid/redesign/aco/docs/faqs.pdf.

23.91 AHI 10 NYCRR § 401.3(a)

Background and justification provided in your request:

(1) 2.a.i. project requirements (4-7); 2.a.ii. project requirements (4-6); 2.a.iv. project requirements (4-6); 2.b.vii. project requirement 10; 2.d.i. project requirement 19; 3.a.i. project requirement 4; 3.a.ii. project requirement (2, 8, and 11); 3.a.iv. project requirement 9; 3.g.i. project requirement 6; and 4.b.ii project requirement 4.

(2) The PPS requests a waiver to forgo prior review, regardless of cost, for acquisition, installation, and modification, and any capital outlay associated with purchase of EHR for PPS Partners.

Response to waiver request:

HIT Standards. Approved. The PPS requested waivers of pertaining to CON review of Health Information Technology (HIT) changes in existing medical facilities. The waiver request is approved to waive 10 NYCRR § 710.1(b) regarding 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.

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

Please note that the Department of Health will publish on its website a list of regulatory waivers that have been approved to assist PPSs in determining whether additional waivers may be appropriate for the activities within a PPS. Additional requests for waivers, as well as any

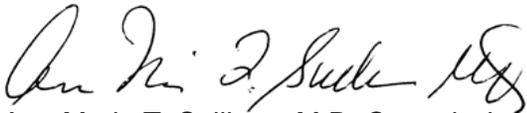
questions regarding the foregoing, may be sent by email to DSRIP@health.ny.gov with Regulatory Waiver in the subject line.

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

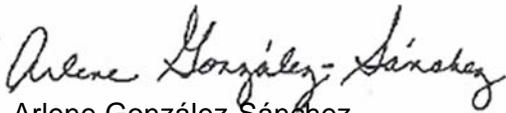
Sincerely,



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



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



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