



Department
of Health

Office of
Mental Health

Office of Alcoholism and
Substance Abuse Services

March 10, 2015

Joseph Conte, Sr. VP for Quality, Risk & Legal Affairs
Richmond Univ Med Center & Staten Island University Hospital
STATEN ISLAND UNIV HOSP / Richmond University Hospital
355 Bard Avenue
Staten Island, NY 10310

Dear Mr. Conte:

The Department of Health (DOH), the Office of Mental Health (OMH), the Office of Alcoholism and Substance Abuse Services (OASAS) are pleased to respond to the request for waivers from certain regulatory requirements submitted under the Delivery System Reform Incentive Payment (DSRIP) Program. This letter responds to the request submitted by Staten Island University Hospital in its capacity as lead for the Richmond University Medical Center Performing Provider System under the Delivery System Reform Incentive Payment (DSRIP) Program.

Pursuant to Public Health Law (PHL) § 2807(20)(e) and (21)(e) and in connection with DSRIP Project Plans and projects under the Capital Restructuring Financing Program which are associated with DSRIP projects, DOH, OMH, and OASAS may waive regulations for the purpose of allowing applicants to avoid duplication of requirements and to allow the efficient implementation of the proposed projects. However, the agencies may not waive regulations pertaining to patient safety nor waive regulations if such waiver would risk patient safety. Further, any waivers approved under this authority may not exceed the life of the project or such shorter time periods as the authorizing commissioner may determine.

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

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

Specific requests for regulatory waivers included in the Richmond University Medical Center PPS Project Plan application are addressed below.

43.01 Richmond

10 NYCRR 400.9, 400.11, 700.3, 18 NYCRR 505.20, 14 NYCRR 36.4, 14NYCRR 504.5, 14 NYCRR Part 815.7

Background and justification provided in your request:

To ease the transition of patients between care levels pursuant to Project 2.b.iv (Care Transitions), Project 2.b.vii. (Hospital-Home Care Collaboration), Project 3.a.iv (Ambulatory Detox) and Project 2b.vii. (INTERACT), the SI PPS will require waivers pertaining to admission, discharge and transfer of patients. All decisions about facility placement are ultimately subject to patient choice.

Response to waiver request:

Department-Transfer and affiliation agreements. No waiver needed. The PPS requested a waiver of 10 NYCRR § 400.9 regarding transfer and affiliation agreements. No waiver is needed as no additional transfer and affiliation agreements are needed provided the PPS has already established such agreements among the partners within the PPS.

OMH-More information needed. OMH seeks additional information clarifying which provisions of their regulations are being sought for waiver, and why the waiver would facilitate this transition. The regulations are protective of individual rights; therefore OMH needs clarification on why a waiver would facilitate the transition for the patient, not the program, and what alternative mechanism of ensuring client rights is proposed. Please provide such information to Keith McCarthy of OMH at Keith.McCarthy@omh.ny.gov.

OASAS-More information needed. OASAS seeks additional information clarifying which provisions of their regulations are being sought for waiver, and why the waiver would facilitate this transition. The regulations are protective of individual rights; therefore OASAS needs clarification on why a waiver would facilitate the transition for the patient, not the program, and what alternative mechanism of ensuring client rights is proposed. Please provide such information to Trishia Allen of OASAS at Trishia.Allen@oasas.ny.gov.

43.02 Richmond 10 NYCRR 401.2(b)

Background and justification provided in your request:

This would enable individuals with chronic illnesses to be visited at home by practitioners employed by the general hospital OP departments and D&TCs. This would be important for Projects 2.b.vii (Hospital-Home Care Collaboration) and 2.b.iv (Care Transitions). Care management is a key element of many of the DSRIP projects, and with the DSRIP target population; it is likely that some of the elements of care management and project implementation may be best accomplished through home visits by physicians, nurses, care managers and other staff from PPS participating partners. This waiver does not implicate patient safety, since licensed facilities or professionals in those fields would provide all services requiring professional licensure.

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.

43.03 Richmond 10 NYCRR 405.9(f)(7))

Background and justification provided in your request:

Department Reg. 405.9(f)(7) requires hospitals to “ensure that no person presented for medical care shall be removed, transferred or discharged from a hospital based upon source of payment.” In view of the potential that the incentive payments for DSRIP Projects could come within the Reg. 405.9(f)(7)’s definition of source of payment, SI PPS requests a waiver of that regulation, so that there can be no question that the SI PPS and its providers can pursue the DSRIP Projects that seek to improve care management and could impact discharge and transfer decisions without violating this regulation. This would affect transferring patients for more appropriate services in many of the DSRIP projects including 3.a.iv. Ambulatory Detox.

Response to waiver request:

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

43.04 Richmond 10 NYCRR 600.9(c)

Background and justification provided in your request:

The DSRIP program provides for each PPS to receive DSRIP incentive payments and distribute those funds to participating partners and others, in accordance with a funds flow approach outlined in the SI PPS DSRIP Application. It is conceivable that an Article 28 entity serving as a co-leader or a participating provider might receive DSRIP Funds for re-distribution to others providers and entities within the PPS. To facilitate smooth operation of the PPS and the processing of DSRIP funding, the SI PPS requests a waiver of Reg. 600.9(c), which limits the sharing of “total gross income or net revenue of a medical facility.” In case DSRIP funds would come within this definition, and to permit sharing of DSRIP funds received by hospitals or other Article 28 facilities in accordance with the SI PPS funds flow methodology, a waiver should be granted. This impacts general PPS operations, and would have no impact on patient safety.

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.

43.05 Richmond 10 NYCRR Part 790

Background and justification provided in your request:

This would expand the geographic areas in which hospices are authorized to operate. This will impact the PPS's ability to implement palliative care expansion through hospice providers not currently licensed to practice on SI through project 3.g.ii.

Response to waiver request:

Expansion of hospice geographic service area. Determination pending.

43.06 Richmond 3ai Department Reg. 401.3(d), and similar OMH and OASAS regulations.

Background and justification provided in your request:

DSRIP Project 3.a.i involves the integration of Primary and BH Services. In addition to physical plant issues (i.e. Interchangeable offices), flexible staffing, and billing, waiver or expedited reviews will be required in order to permit primary care facilities to add behavioral health services, and vice versa. Specifically, waiver is requested of Department Reg. 401.3(d), and similar OMH and OASAS regulations. In addition, Proposed OMH Reg. 14-599-1 should add provisions for an expedited process and for recognition of the combined services for reimbursement purposes. This would have no impact on patient safety.

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.

Integrated Services Billing. Approved contingent upon following the Integrated Services Model outlined in Appendix A to this letter. 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 including which specific provisions of the regulations they are seeking to waive at which specific providers ;
- 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.

43.07 Richmond NYCRR 400.11 and 700.3

Background and justification provided in your request:

This regulation governs the assessment of Long Term Care patients. Waivers will be beneficial as it relates to the goals of Project 2bvii. INTERACT.

Response to waiver request:

PRI requirement. Approved. 10 NYCRR 400.11(a) and 700.3 requires Hospital/Community PRI or PRI as well as the SCREEN. 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. We will waive the PRI requirement in 400.11(a) provided that the provider notify, and obtain approval from, the department for an alternative screening tool.

43.08 Richmond NYCRR 405.19(g)

Background and justification provided in your request:

The PPS members will pursue waivers regarding limitation on the number of observation beds, and certain approvals as it may support the overall goals of DSRIP to reduce avoidable admissions.

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.

43.09 Richmond PHL §2807(20)(e) and (21)(e) and (21)(e)

Background and justification provided in your request:

The PPS will require a corporate structure that incorporates some allowances related to 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

43.10 Richmond Waiver of 10 NYCRR 405.3(f)

Background and justification provided in your request:

SI PPS, LLC and its PMO will be providing a range of services to the partners, including coordination of care management, support in project implementation, collection and analysis of

data, and other PPS administrative functions. While SI PPS does not view these centralized functions as constituting traditional "management contracts," and while each facility will retain its existing governance and management structure, services provided by the PMO might be viewed as "management" services that might require Department approval under Department Reg. 405.3 initially and every 3 years. Waiver is sought so that it will be clear that Department approval of PPS administrative activities do not require such approval. This waiver may affect multiple projects involving the support and coordination of the SI PPS PMO.

Response to waiver request:

Administrative Services. No waiver needed. The PPS requested waivers of 10 NYCRR §§ 405.3(f). No waiver is needed to the extent the PPS and its contracting entities are performing administrative functions for purposes of administering PPS activities. However, if the contracting entities are assuming primary responsibility for the managing the day-to-day operations of an entire facility, a management contract is required to be reviewed by the department of Health.

43.11 Richmond

Background and justification provided in your request:

Waivers that provide flexibility around existing limitations on the ability of NP's to authorize homecare will assist the PPS in meetings is goals of reducing admissions for patients in home care that are at risk for readmission.

Response to waiver request:

Home care and NPs. No waiver needed. NPs may already authorize homecare services.

43.12 Richmond

Background and justification provided in your request:

Flexibility around the limitation on suboxone patients and the ability for Nurse Practitioners to prescribe suboxone will be important in furthering the goal of the PPS in expanding ambulatory detox (Project 3.a.iv Ambulatory Detox/Withdrawal Management).

Response to waiver request:

Suboxone and NPs. Denied. We do not have the ability to waive this as it is a federal requirement.

43.13 Richmond 3ai

Background and justification provided in your request:

Scheduling primary care and psychiatry visits on the same day is more convenient for patients, and may affect Project 3.a.i (Integration of Medical and Primary Care) and other projects seeking to provide multiple services as efficiently as possible to high risk patients. Payment for same day, multi-specialty billing is needed, and especially for any guidance or regulations that support MCO protocols that limit payment for same day services.

Response to waiver request:

Integrated Services Billing. Approved contingent upon following the Integrated Services Model outlined in Appendix A to this letter. As noted in Appendix A, the use of this model is contingent upon, among other things:

- submission of an application by the PPS with the identification all providers involved in such model including which specific provisions of the regulations they are seeking to waive at which specific providers ;
- 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.

43.14 Richmond 10 NYCRR 86-4.9, 86-8.14, and 401.2

Background and justification provided in your request:

Waiver for 10 NYCRR 86-4.9, 86-8.14, and 401.2, would allow for consideration of reimbursement of home visit types of services which are important to 2.b.vii (Hospital-Home Care Collaboration) and 2.b.iv (Care Transitions).

Response to waiver request:

Billing of off-site services. Determination pending. Reimbursement for the provision of services by practitioners affiliated with Article 28 providers to provide services outside of the certified service site 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.

43.15 Richmond

Background and justification provided in your request:

Waivers that provide flexibility around existing OASAS guidelines to accommodate less restrictive ambulatory detox staffing ratios will support the PPS's ability to expand ambulatory detox (Project 3.a.iv Withdrawal Management).

Response to waiver request:

Approvable on a case-by-case basis. The OASAS Medical director would need to review particular protocols as patient safety may be implicated. Please provide such information to Trishia Allen of OASAS via email at Trishia.Allen@oasas.ny.gov.

43.16 Richmond

Background and justification provided in your request:

Telemedicine allows for clinic access for clients where travel to a clinic is difficult or impossible, especially in rural areas, for patients who have difficulty travelling, or in areas where transportation is difficult; allows immediate clinic access when a rapid evaluation is needed; and allows a patient in a primary care office to access psychiatry through telemedicine. Currently proposed changes to OMH regulations 599.17 involving telemedicine do not provide sufficient regulatory relief as it requires that both the client and the prescriber must physically be in an OMH clinic. Similarly, Department regulations should be waived or amended to permit telemedicine between non-Article 28 sites. Telemedicine will assist with Project 2.b.iv (Care

Transitions to Reduce 30 day admissions), 2.di (Engage Medicaid low/non users and the uninsured) and other clinical projects.

Response to waiver request:

Telepsychiatry- More information needed. OMH supports any telepsychiatry services to be provided pursuant to the standards of the soon-to-be-adopted OMH regulation (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.

Telemedicine-Waiver is not needed. Department regulatory waiver is not needed as current regulations do not prohibit telemedicine between non-Article 28 sites.

43.17 Richmond Department Reg. 401.3, 712-2.4, 713-4.3, 713-4.4, 713-4.9, 713-4.10 714.4, 715-2.4, 717.2; OMH Regs 599.5 and 599.12; and OASAS Regs. 814.2, 814.3, 814.6 and 814.7.

Background and justification provided in your request:

To facilitate construction and placing renovated facilities in service as quickly as possible, the SI PPS requests that the agencies expedite approvals or waive CON, PAR and other approvals and permit architectural self-certification, and similarly waive the need methodology for construction and equipment purchases related to DSRIP projects, Regulations potentially to be waived are Department Reg. 401.3, 712-2.4, 713-4.3, 713-4.4, 713-4.9, 713-4.10 714.4, 715-2.4, 717.2; OMH Regs 599.5 and 599.12; and OASAS Regs. 814.2, 814.3, 814.6 and 814.7. Patient safety will not be impacted, if self-certification is permitted. These waivers impact on Project 3.a.i (Integration of Primary and Behavioral Health Services) and possibly others in which construction may be required at one or more PPS provider locations.

Response to waiver request:

Department- Construction Standards. Denied. The PPS requested waivers of §§ 401.3 and 711 through 715, which set forth construction standards. Due to patient safety concerns, these regulations cannot be waived. However, the Department will expedite the review of projects associated with DSRIP Project Plans to the extent possible.

OASAS- More information needed. OASAS seeks additional information clarifying the proposal as it relates to what type of services will be provided and where the services will be located. Please provide such information to Trishia Allen of OASAS via email at Trishia.Allen@oasas.ny.gov.

OMH-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.

43.18 Richmond

Background and justification provided in your request:

Although the agencies have indicated that a simple waiver is not available for this issue, we understand that the Department, OMH and OASAS plan to coordinate on the development of a model information release consent form for use by PPS providers that would cover all forms of patient information exchanged by providers. In that process, to facilitate information sharing among providers in connection with care management and other PPS collaborations, we suggest that the agencies seek clarification of SHIN-NY guidance be issued to facilitate information sharing, including "opt-out" approaches for clinical information exchange, and clarification that sharing of information among PPS Participating Providers in connection with DSRIP constitutes permitted sharing of information for treatment purposes that does not require consent.

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.

43.19 Richmond Department Reg. 710.1 OMH Reg. 551 pertaining to prior approval review for quality and appropriateness; and OASAS Reg. 810

Background and justification provided in your request:

While the agencies have reduced the number of service changes that require CON or other reviews, we request that the agencies waive or expedite approvals of changes in services to the extent necessary to implement a DSRIP Project. Examples include adding behavioral health services at an FQHC site under Project 3.a.i, and possibly others where there will be a shift in utilization from inpatient to community based services. Waivers would include: Department Reg. 710.1 OMH Reg. 551 pertaining to prior approval review for quality and appropriateness; and OASAS Reg. 810 pertaining to establishment, incorporation and certification of providers of chemical dependence services.

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.

43.20 Richmond Department Reg 710.9

Background and justification provided in your request:

In order to make facilities available as soon as construction or renovations are completed, we request that the agencies waive pre-opening inspections or expedite scheduling of pre-opening inspections for renovations or construction in existing facilities that otherwise would be required under Department Reg 710.9. This affects projects in which construction may be required at one or more PPS provider locations.

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.

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

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