



Department
of Health

Office of
Mental Health

Office of Alcoholism and
Substance Abuse Services

March 10, 2015

Victor Politi, MD, FACP, FACEP
Nassau University Medical Center
NASSAU UNIVERSITY MEDICAL CEN
2201 Hempstead Turnpike
East Meadow, New York 11554

Dear Dr. Politi:

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 Nassau University Medical Center in its capacity as lead for the Nassau University Medical Center PPS under the Delivery System Reform Incentive Payment (DSRIP) Program.

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

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

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

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

14.01 NUMC 2.a.i

Background and justification provided in your request:

The Nassau Queens PPS (NQP) and potentially sub-groups within the PPS intend to apply for COPA and/or ACO status for NQP, pursuant to the pending COPA Regulations, when finalized, using the application forms released by the Department on December 5, 2014. Additional time will be needed to complete the COPA and/or ACO application because extensive market studies that are required are different than those for the DSRIP Community Needs Assessment. The protection from regulatory challenges based on antitrust and other laws may be crucial to implementation of the DSRIP Program by NQP, which by definition requires extensive collaboration to coordinate care and health efforts with respect to the Medicaid population, as well as funds flow among entities that might otherwise be viewed as competitors or referral sources. These waivers will impact on Project 2.a.i (IDS), and on all other PPS Projects.

Response to waiver request:

Not applicable. No regulatory waiver requested.

14.02 NUMC 2.a.i

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 NQP's DSRIP Application. It is conceivable that an Article 28 entity serving as a hub 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, NQP 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 NQP's funds flow methodology, a waiver should be granted.

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.

14.03 NUMC 2.a.i Waiver of 10 NYCRR 405.3(f)

Background and justification provided in your request:

NQP and its Project Management Office (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 NQP 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 NQP and 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 impacts project 2.a.i (IDS) and general PPS operation.

Response to waiver

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.

14.04 NUMC 2.a.i

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. Impacts Project 2.a.i (IDS) and all other projects that incorporate patient engagement, care management and outreach.

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.

14.05 NUMC 2.b.iv, 3.a.ii , 3.b.i , and 3.c.i Department Reg. 401.2(b)

Background and justification provided in your request:

Department Reg. 401.2(b) provides that an operator may provide services listed on its operating certificate only for the designed site of operation. 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. Specifically, projects 2.b.iv (Care Transitions), 3.a.ii (Behavioral Health Community Crisis Stabilization Services), 3.b.i (Disease Management – Cardiovascular, and 3.c.i (Disease Management – Diabetes).

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.

14.06 NUMC 2.b.ii, 3.a.i, 3.a.ii 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, NQP 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. These waivers impact on Projects 2.b.ii (Co-located Primary Care); 3.a.i (Integration of Primary and Behavioral Health Services); and 3.a.ii (Behavioral Health Crisis Stabilization Services), and possibly others in which construction may be required at one or more PPS provider locations.

Response to waiver request:

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 seeks additional information specifying the regulatory provision to be waived and the justification for waiving. OASAS would be willing to waive those provisions not implicating patient safety. Building codes contained in 814.2 would implicate patient safety.

14.07 NUMC 3.a.i, 2.b.ii 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.

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 co-location of primary care and ED services (Project 2.b.ii).

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

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.

14.08 NUMC 2.b.ii, 3.a.i, 3.a.ii 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 impacts Project 2.b.ii (ED Care Triage); 3.a.i (Integration of Primary and Behavioral Health Services); and 3.a.ii (Behavioral Health Crisis Stabilization Services).

Response to waiver request:

Pre-Opening Surveys. Denied. The PPS requested waivers pertaining to CON pre-opening surveys. These requests are denied, as pre-opening surveys pertain to patient safety. However, the Department will expedite pre-opening surveys connected with DSRIP projects to the extent possible.

14.09 NUMC 2.b.ii

Background and justification provided in your request:

Scheduling primary care and psychiatry visits on the same day is more convenient for patients, and captures the essence of Project 2.b.11 (Co-Location of Primary Care). While this is permissible under Medicaid, not all Managed Care Organizations concur. Payment for same day, multi-specialty billing is needed, and the agencies are requested to waive any guidance or regulations that support the MCO position.

Response to waiver request:

Not applicable as regulatory waiver not requested. Regulations do not direct how managed care plans are to pay for integrated services. The Department will work with managed

care plans to insure they understand the integrated services care model and reimburse providers for the full complement of behavioral and physical health services when appropriate.

14.10 NUMC 3.a.ii OMH regulations 599.17

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 3.a.ii (Behavioral Health Crisis Stabilization Services).

Response to waiver request:

Department-No waiver needed. There are no regulations in place that disallow the practice of telemedicine in non-Article 28 settings. Medicaid reimbursement for telemedicine is currently limited to Article 28 settings, however an expanded Medicaid telemedicine coverage policy is under development that will allow for reimbursement in additional settings and with additional provider types.

OMH- more information needed. OMH supports any telepsychiatry service to be provided pursuant to the standards of the soon-to-be adopted OMH regulation (14 NYCRR 599.17). It is not clear what provisions of the regulation may be preventing the PPS from proceeding with the desired project. Please contact Keith McCarthy of OMH via email at Keith.McCarthy@omh.ny.us with more information.

14.11 NUMC 3.a.i 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.

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.

14.12 NUMC Department 400.9 (transfer and affiliation agreements), 400.11 and 700.3 (assessment of LTC patients), 405.9 (admission and discharge) and 415.38 (long term ventilator dependent residents; Social Services Reg. 505.20 (alternate care); OMH. 36.4 (community placement of patients discharged or conditional release) and 504.5 (community placement after behavioral health discharge); and OASAS 815.7 (discharge).

Background and justification provided in your request:

NQP requests waivers to facilitate placing patients into facilities with the highest quality and most well-coordinated care. While decision-making tools designed to help patients and families refocus the decision discourse from geography to quality exist, current regulations constrain discussions in a way that inhibits this approach. To achieve greater flexibility, NQP is requesting waivers of the following regulations: Department 400.9 (transfer and affiliation agreements), 400.11 and 700.3 (assessment of LTC patients), 405.9 (admission and discharge) and 415.38 (long term ventilator dependent residents; Social Services Reg. 505.20 (alternate care); OMH. 36.4 (community placement of patients discharged or conditional release) and 504.5 (community placement after behavioral health discharge); and OASAS 815.7 (discharge).

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.

Department-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.

Department-PRI requirement. Approved. 10 NYCRR 400.11(a) 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.

OMH-36.4 (community placement of patients discharged or conditional release) and 504.5 (community placement after behavioral health discharge). More information needed. 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 provide more information to Keith McCarthy of OMH via email at Keith.McCarthy@omh.ny.gov.

OASAS-815.7 (discharge) – Denied. More information needed. It is unclear why the waiver would facilitate this transition. The regulations are protective of individual rights; therefore, before granting any waiver related thereto, OASAS 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 provide more information to Trishia Allen of OASAS via email at Trishia.Allen@oasas.ny.gov.

14.13 NUMC 2.a.i, 2.b.ii, 2.b.iv, 2.b.vii Department Reg. 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, NQP requests a waiver of that regulation, so that there can be no question that NQP 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 waiver relates to DSRIP Projects 2.a.i (IDS), 2.b.ii (ED Triage), 2.b.iv (Care Transitions and 2.b.vii (INTERACT), and does not present any risk to patient safety.

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.

14.14 NUMC 2.a.i, 2.b.ii, 2.b.iv Department Reg. 790

Background and justification provided in your request:

NQP requests a waiver of the hospice need methodology set forth in Department Reg. 790, in order to expand the geographic areas in which hospices participating in NQP's DSRIP Projects are authorized to operate. This waiver will ensure that existing hospices have the ability to expand their geographical scope to the extent necessary to address the needs of individuals for whom the PPS is responsible.

Response to waiver request:

Determination pending

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
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