



December 2, 2016

Stony Brook University Hospital P.P.S.
Jennifer Jamilkowski
Director of Planning
Stony Brook University Hospital
101 Nicolls Road
Stony Brook, New York 11794

Dear Ms. Jamilkowski:

The New York State Department of Health (Department), the Office of Mental Health (OMH), the Office of Alcoholism and Substance Abuse Services (OASAS) and the Office for People with Developmental Disabilities (OPWDD) 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 the Stony Brook University Hospital in its capacity as the lead for Stony Brook Performing Provider System (PPS).

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 for 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 is 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.

The specific requests for regulatory waivers are addressed below.

1 Stony Brook 10 NYCRR 600.9(c) 3.a.i

Background and justification provided in your request:

This regulation relates to the sharing of the total gross income or net revenue of a medical facility by an individual, partnership or corporation which has not received establishment approval. Successful Project implementation requires that the PPS have the ability to flow funds to non-established operators since the PPS and Partner Organizations may share in distribution of DSRIP funding as part of sharing a patient population and participating in DSRIP services. Project 3.a.i. incentivizes providers to provide such care by tying funds flow to the success and meeting of project metrics by each partner in the PPS.

Response to waiver request:

Revenue Sharing. Approved. The PPS requested a waiver of 10 NYCRR 600.9(c), pertaining to revenue sharing. The waiver is approved only to the extent that the regulation otherwise would prohibit providers from receiving DSRIP incentive payments distributed by the PPS Lead utilizing the DSRIP flow of funds protocol.

2 Stony Brook 10 NYCRR 670.1(a), 10 NYCRR 670.1(b), 10 NYCRR 670.1(c) 3.a.i.

Background and justification provided in your request:

These regulations set forth a list of factors for determining public need for the establishment of medical facilities, describe the extensive evaluation process for public need review, and requires a public need analysis to include determination of appropriate service areas. The referenced regulations impose additional administrative burdens on the PPS. The waiver is requested to relieve the PPS from the exhaustive requirements of the need for new CONs and the extensive requirements as they relate to the methodologies used to determine public need. This waiver will allow the PPS to expedite the integration of primary care and behavioral services and will expand the PPS' ability to meet patient needs in locations other than the ER, such as primary care and behavioral health sites.

Response to waiver request:

Public Need and Financial Feasibility. Approved. The PPS requested waivers of 10 NYCRR 670.1, 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 needs to be filed through NYSE-CON and provider compliance will still be reviewed.

3 Stony Brook 10 NYCRR 405.2(e) (3), 10 NYCRR 405.4 3.a.i.

Background and justification provided in your request:

These regulations set forth the requirement that a governing body establishes medical staff bylaws which include criteria for the delineation of privileges and mandate that medical staff by laws set forth criteria and procedures for credentialing.

Response to waiver request:

Approved. The PPS requested a waiver of 10 NYCRR 405.2 (e) and 10 NYCRR 405.4(c) (5) for the purposes 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.

4 Stony Brook 14 NYCRR Part 599 3.a.i.

Background and justification provided in your request:

These regulations govern the regulation and quality control of services for the Mentally Disabled, Chemical Dependence Services, and Compulsive Gambling Services. Regulations under the referenced statutes interfere with the proposed operation and stated goals of 3.a.i by impeding the co-location of services at behavioral health sites as a consequence of prohibiting such co-location under a single license or certification issued under the Public Health Law (PHL) or Mental Health Law (MHL). As stated above, primary care services will be expanded to eight behavioral health sites. The inability to co-locate services without a waiver may preclude the project from being implemented.

Response to waiver request:

No Waiver Needed. Please see attached guidance relative to allowable initiatives relative to “Shared Space/Co-Location”. No waiver is needed to the extent providers follow the attached guidance. The Department/OMH/OASAS do not have the authority to issue any regulatory waivers beyond what is allowable by federal regulations and policy.

5 Stony Brook 14 NYCRR 600.2(c) 3.a.i.

Background and justification provided in your request:

This regulation requires Department approval for behavioral and/or substance use providers to operate primary care under the oversight of the agency regulating them (OMH, OASAS, OPWDD). The referenced regulation interferes with the project by prohibiting behavioral and/or substance use providers from operating primary care under the oversight of the agency regulating it without the approval of the Department. The referenced regulation will impede the provision of integrated services by licensed providers who expand their scope of services and will cause additional delay pending Department approval. One of DSRIP’s main priorities is to stimulate the integration of primary care, behavioral health and/or substance use treatment services. A waiver of this regulation would allow this vision to be most efficiently accomplished through a single provider with a single licensing agency at certain sites of service.

Response to waiver request:

No Waiver Needed. In order to facilitate integration of primary care and behavioral health services for purposes of Project 3.a.i, the Department of Health (Department) and the Office of Mental Health (OMH) will raise their Licensure Thresholds and the Office of Alcoholism and Substance Abuse Services (OASAS) will implement a Licensure Threshold for outpatient providers licensed or certified by the Department, OMH or OASAS that are part of the DSRIP project, permitting such providers to integrate primary care and behavioral health services under

a single license or certification so long as the service to be added is not more than 49 percent of the provider's total annual visits ("DSRIP Project 3.a.i Licensure Threshold") and the patient initially presents to the provider for a service authorized by such provider's license or certification.

OPWDD - More Information Needed. If you are seeking a regulatory waiver to an OPWDD regulation, please resubmit request with specific regulatory citation, justification and description of impact on patient safety. While the Department, OMH and OASAS have determined that no additional waivers are needed if providers are integrating services under the specified model, OPWDD needs more information about how this request applies to OPWDD governed services.

6 Stony Brook 10 NYCRR 709, 14 NYCRR 551, 14 NYCRR 810 3.a.i.

Background and justification provided in your request:

These Regulations set forth necessary factors and procedure for evaluation and public need analysis for the establishment of a new medical facility, regulate prior approval reviews for quality and appropriateness, and regulate the establishment of chemical dependence service providers. While the agencies have reduced the number of service changes that require CON or other reviews, the PPS requests that the agencies waive or expedite approvals of changes in services to the extent necessary to implement the Project. This waiver would remove administrative burdens and expedite the time in which behavioral health services could be provided at FQHC sites.

Response to waiver request:

Department - Public Need and Financial Feasibility. Approved. The PPS requested waivers with respect to the public need and financial feasibility components of the CON process. Waiver is approved for 10 NYCRR §709, 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 needs to be filed through NYSE-CON and provider compliance will still be reviewed.

OMH - 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.

OASAS - Public Need and Financial Feasibility. Approved. To the extent that the proposal would implicate federal requirements, we are not able to waive such. The public need and financial feasibility components of the OASAS certification process are waived, however an application still needs to be filed and provider compliance will still be reviewed.

7 Stony Brook 10 NYCRR 86-8 3.a.i

Background and justification provided in your request:

This Regulation prohibits payment on a second claim to a provider that submits multiple fee for service claims on the same date of service or within the same or episode. Given the severely compromised mental and physical health condition of the targeted patient population,

the intensity of the necessary care and the need for care coordination, the PPS needs adequate funding to achieve financial sustainability. Granting this waiver would allow each claim for multiple services provided to a patient on the same day to be paid at the full fee-for-service amount.

Response to waiver request:

Integrated services. No Waiver Needed. In order to facilitate integration of primary care and behavioral health services for purposes of Project 3.a.i, the Department and the Office of Mental Health (OMH) will raise their Licensure Thresholds and the Office of Alcoholism and Substance Abuse Services (OASAS) will implement a Licensure Threshold for outpatient providers licensed or certified by the Department, OMH or OASAS that are part of the DSRIP project, permitting such providers to integrate primary care and behavioral health services under a single license or certification so long as the service to be added is not more than 49 percent of the provider's total annual visits ("DSRIP Project 3.a.i Licensure Threshold") and the patient initially presents to the provider for a service authorized by such provider's license or certification.

8 Stony Brook 14 NYCRR 810, 814-857 3.a.i

Background and justification provided in your request:

These Regulations set forth OASAS licensing and ongoing operating procedures. The referenced regulations prohibit a PHL Article 28 primary care provider from providing substance use disorder services without being certified by OASAS. The PPS seeks to take advantage of the implementation of the Licensure Threshold for Substance Abuse Disorder Services, which permits a PHL Article 28 primary care provider to provide substance abuse disorder services under its license without being certified by OASAS if less than 49 percent of its total annual visits are for substance abuse disorder services.

Response to waiver request:


Integrated Services. No Waiver Needed. In order to facilitate integration of primary care and behavioral health services for purposes of Project 3.a.i, the Department and the Office of Mental Health (OMH) will raise their Licensure Thresholds and the Office of Alcoholism and Substance Abuse Services (OASAS) will implement a Licensure Threshold for outpatient providers licensed or certified by the Department, OMH or OASAS that are part of the DSRIP project, permitting such providers to integrate primary care and behavioral health services under a single license or certification so long as the service to be added is not more than 49 percent of the provider's total annual visits ("DSRIP Project 3.a.i Licensure Threshold") and the patient initially presents to the provider for a service authorized by such provider's license or certification.


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

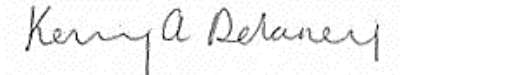
Thank you for your cooperation with this initiative. We look forward to working with you to transform New York's delivery system.

Sincerely,


Howard Zucker, M.D., J.D.
Commissioner 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


Kerry Delaney
Acting Commissioner
New York State Office for People With
Developmental Disabilities