



March 12, 2015

Jennifer Jamilkowski  
Director of Planning  
Stony Brook University Hospital  
UNIVERSITY HOSPITAL  
101 Nicolls Road  
Stony Brook, New York 11794

Dear Ms. Jamilkowski:

The 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 University Hospital in its capacity as lead for the Stony Brook University Hospital 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, OASAS and OPWDD 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 Stony Brook University Hospital PPS Project Plan application are addressed below.

**16.01 Stony Brook University Hospital 2.a.i, 2.b.iv, 3.a.i 10 NYCRR 34-1.3; 10 NYCRR 34-2.3; 10 NYCRR 34-2.4 Currently Prohibited Business Practices**

Background and justification provided in your request:

- 10 NYCRR 34-1.3 prohibits practitioners from making referrals to a healthcare provider authorized to provide such services where such practitioner has a financial relationship with such health care provider.
- 10 NYCRR 34-2.3 prohibits health services purveyors from accepting payment/consideration from a clinical laboratory (CL) for the referral for the performance of CL services.
- 10 NYCRR 34-2.4 prohibits a CL from giving payment/consideration to a health services purveyor for the performance of CL services.

The referenced regulations interfere with the projects by prohibiting the referral of patients to appropriate facilities. Such regulations will deter PPS providers from referring patients to settings for needed care, in fear of engaging in prohibited practices. DSRIP requires that the PPS include providers of all facets of healthcare to deliver care through an integrated network of providers who understand the importance of greater interconnectivity to address patient issues as a whole. By coordination/referral to appropriate healthcare settings, such providers are able to prevent fragmented care that fails to address the patient's overall health or may be duplicative.

Response to waiver request:

**Denied.** This regulation cannot be waived as it is mandated by statute, which we do not have the authority to waive.

**16.02 Stony Brook University Hospital 2.a.i 10 NYCRR 600.9(c) Revenue Sharing**

Background and justification provided in your request:

10 NYCRR 600.9(c) regulates 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. The referenced regulation interferes with the proposed operation and stated goals of 2a.i by prohibiting sharing of revenue which is contrary to the intent of DSRIP, which monetarily incentivizes the PPS and its partners to work as an integrated network and act as a team to deliver comprehensive care. Further, partners within the PPS would be unable to re-distribute DSRIP funds amongst other partners/providers as such disbursement might be considered an illegal kickback. Accordingly, a waiver of these regulations is required to permit successful Project implementation and achievement of Project objectives. Without such a waiver, successful Project implementation will not be feasible.

Response to waiver request:

**Revenue Sharing. Approved.** The waiver is approved to the extent that regulations otherwise would prohibit providers from receiving DSRIP incentive payments distributed by the PPS Lead.

**16.03 Stony Brook University Hospital 2.a.i 10 NYCRR 600.9(d); 10 NYCRR 405.3(f) Management Contracts**

Background and justification provided in your request:

- 10 NYCRR 600.9 states that a medical facility may not contract for management services with a party which has not received establishment approval.
- 10 NYCRR 405.3(f) specifically prohibits contracting with an entity to assume the day-to-day operations of the entire facility or a unit of the facility.
- 14 NYCRR 810.12 regulates the criteria and procedures for approval of management contracts.

The referenced regulations interfere with the proposed operation and stated goals of 2.a.i by interfering with the ability of the PPS to adequately create an integrated structure where particular vital operations are contracted to a third party to ensure that PPS providers are able to focus on provision of clinical care. Accordingly, a waiver of the regulations is required to permit successful Project implementation and achievement of Project objectives. Without such a waiver, successful Project implementation will not be feasible.

Response to waiver request:

**Administrative Services. No waiver needed.** The PPS requested waivers of 10 NYCRR §§ 600.9 and 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).

**16.04 Stony Brook University Hospital 3.a.i 14 NYCRR 810.12(a) Management Contracts**

Background and justification provided in your request:

14 NYCRR 810.12(a) regulates the criteria and procedures for approval of management contracts including submission of each contract to OASAS for approval and demonstrating need for the management contractor. The referenced regulation interferes with the proposed operation and stated goals of 3.a.i by interfering with the ability of the PPS providers to adequately create an integrated structure where particular vital operations are contracted to a third party to ensure that providers are able to focus on provision of clinical care. Accordingly, a waiver of the regulations is required to permit successful Project implementation and achievement of Project objectives. Without such a waiver, successful Project implementation will not be feasible.

Response to waiver request:

**Management Contracts. Denied by OASAS.**

**16.05 Stony Brook University Hospital 2.a.i 10 NYCRR 405.1(c) Active Parent**

Background and justification provided in your request:

10 NYCRR 405.1(c) states that, “any person... or other entity with the authority to operate a hospital must be approved for establishment by the [Public Health and Health Planning Council] unless otherwise permitted to operate by the Public Health Law...” An operator is defined as an entity of a hospital who has decision-making authority over any of the active parent powers, such as approval of hospital contracts for management or for clinical services, appointment or dismissal of hospital management-level employees and medical staff, approval of hospital operating and capital budgets, and adoption or approval of hospital operating policies and procedures. It also regulates the approval by the Public Health and Health Planning Council (PHHPC) of the operator of a hospital. The referenced regulation interferes with the proposed operation and stated goals of 2.a.i by interfering with the ability of the PPS to adequately create an integrated structure where structure and protocols are decided by a PPS governing body with the consultation of individuals, representative of the providers within the PPS. This regulation relegates such authority to entities that have been approved for establishment and restricts the PPS lead agency, Stony Brook University Hospital (SBUH), and other PPS providers from establishing an internal structure which may involve one or more of the functions listed above, for purposes of implementing other project plans. Accordingly, a waiver of the regulation is required to permit successful Project implementation and achievement of Project objectives. Without such a waiver, successful Project implementation will not be feasible.

Response to waiver request:

**Administrative Services. No waiver needed.** The PPS requested waivers of 10 NYCRR §§ 600.9 and 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).

#### **16.06 Stony Brook University Hospital 2.b.iv 10 NYCRR 400.9(a) Transfer and Affiliation Agreements**

Background and justification provided in your request:

10 NYCRR 400.9(a) regulates the discharge or transfer of any patient or resident. The operator of the transferring/discharging facility must have in place a transfer and/or affiliation agreement with one or more facilities with valid operating certificates and one or more home health agencies certified by the Department and serving a similar geographic area of coverage. The referenced regulation interferes with the proposed operation and stated goals of 2.b.iv by requiring PPS provider to have in place transfer and/or affiliation agreements, approved by the Department, which are duplicative to the agreements already in place with these provider/facilities through participation in the PPS. These PPS participation agreements ensure that partners will work together to achieve the goals of DSRIP and have in place compliance protocols to ensure adequate patient care and safety.

Response to waiver request:

**Admission, Transfer and Discharge. No waiver needed.** 10 NYCRR § 400.9 and 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.

**16.07 Stony Brook University Hospital 3.a.i 14 NYCRR 573.1 OMH- Operating Certificate Issuance and Limitation**

Background and justification provided in your request:

14 NYCRR 573.1 regulates the issuance of an operating certificate (Certificate) by OMH to operate a mental health program such as a clinic and a comprehensive psychiatric emergency program (CPEP). Initial and subsequent Certificates may not be issued for a period to exceed three years. The referenced regulation interferes with the proposed operation and stated goals of 3ai by requiring OMH licensed providers who are collaborating with primary care providers to obtain a satellite Certificate from OMH for the primary care setting. The period of time required for issuance of such Certificate is unclear, as the OMH will likely be inundated with similar applications from other PPSs. Nonetheless, the typical time period for issuance is approximately 3 to 4 months which will inhibit the PPS's ability to engage patients during the time the issuance is pending. Additionally, the Certificate is effective for a period not to exceed three years; as DSRIP is a five-year program, the PPS will also have the administrative burden to apply for a subsequent renewal. Accordingly, a waiver of the regulation is required to permit successful Project implementation and achievement of Project objectives. Without such a waiver, successful Project implementation will not be feasible.

Response to waiver request:

**Denied.** The maximum duration for an OMH-issued operating certificate is three years and OMH is not entertaining any requests to eliminate this requirement due to patient safety concerns.

**16.08 Stony Brook University Hospital 2.a.i, 3.a.i 14 NYCRR § 599.3(d), 599.4(r) & (ab), 599.5(f); OMH- Certification for Clinical Treatment Programs**

Background and justification provided in your request:

The cited regulations regulate the certification of clinical treatment programs, specifically promulgating the requirements for satellite clinics. This includes licensed diagnostic and treatment centers (D&TCs) that provide more than 10,000 mental health visits annually, or for which mental health visits comprise over 30 percent of the annual visits. Requirements include obtaining a Certificate, pursuant 14 NYCRR 551, compliance with OMH's proscribed methods of staff supervision, treatment planning, review of treatment plans, and record maintenance, and OMH notification for change in hours of operation. The referenced regulations interfere with the proposed operation and stated goals of 2.a.i and 3.a.i by discouraging PCPs and other Article 28/31 facilities and mental health services to integrate. Specifically, the waiver is needed for the PPS to add services in existing provider locations without undue delay. Moreover, primary care sites, which could serve patients with mental health issues in an integrated manner, will be deterred from offering such services as to avoid the duplicative burden of complying with both Department and OMH requirements. Deterrence of this kind will hinder the achievement of the goals of this Project as integrated primary and mental health care is necessary to improve the overall health outcomes of the Medicaid population.

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.

**16.09 Stony Brook University Hospital 3.a.i 14 NYCRR 599.9; 14 NYCRR 599.10; 14 NYCRR 599.11; 14 NYCRR 599.12(a) OMH- Staffing, Treatment etc.**

Background and justification provided in your request:

- 14 NYCRR 599.9 regulates staffing of clinical treatment programs including the appropriate number of staff, types and necessary qualifications, and OMH discretionary approval of qualified staff, as appropriate.
- 14 NYCRR 599.10 regulates treatment planning that includes necessary documentation, time periods for completion, and periodic review.
- 14 NYCRR 599.11 regulates case records including necessary documentation and confidentiality.
- 14 NYCRR 599.12(a) regulates premises requirements including arrangement of spaces, program capacity, and appropriate furnishings.

The referenced regulations interfere with the proposed operation and stated goals of 3.a.i by requiring OMH licensed providers who collaborate with PCPs to comply with proscribed requirements. In addition to the duplicative nature of requiring OMH licensed providers collaborating with PCPs to comply with these requirements, such compliance may contribute to confusion among professionals and staff in such settings who will be mandated to comply with Department and OMH. These regulations will discourage PCP and mental health partnerships which is counterproductive to the goals of this Project.

Response to waiver request:

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

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

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

**16.10 Stony Brook University Hospital 3.a.i, 4.a.ii  
of Outpatient Programs**

**14 NYCRR 587.5 OMH- Operations**

Background and justification provided in your request:

14 NYCRR 587.5 regulates the operation of outpatient programs, specifically, the requirement to obtain a Certificate that is effective for a term up to three years. Out-patient programs are required to be separately identifiable, and comply with the requirements of the Certificate, as proscribed by 14 NYCRR 551, including hours of operation, program capacity, and population served. The referenced regulation interferes with the proposed operation and stated goals of 3.a.i and 4.a.ii by requiring that the PPS submit an application for a Certificate for each outpatient program it seeks to establish. Saddled with thousands of applications for outpatient programs, there will likely be a delay in approval as the State will have to process these applications and plan for inspections and re-certifications accordingly. Delay in approval will hinder the PPS's ability to implement the vital components of the Projects.

Response to waiver request:

**Public Need and Financial Feasibility. Approved.** A site-specific project application will still need to be submitted and reviewed by OMH for a determination of character/competency and/or any environmental review, but the provider will not need to satisfy a determination of public need nor financial feasibility.

**16.11 Stony Brook University Hospital 3.a.i, 4.a.ii 14 NYCRR 85.4 Operation of  
Outpatient Facilities For the Mentally Disabled**

Background and justification provided in your request:

14 NYCRR 85.4 regulates the operation of outpatient facilities for the mentally disabled by any clinic, center, institute, hospital, school, institution or other place operated by a corporation. This regulation requires that such a facility must obtain a Certificate that is effective for a period not to exceed two years. The referenced regulation interferes with the proposed operation and stated goals of 3.a.i and 4.a.ii by requiring that the PPS submit Certificate applications for each outpatient facility it intends to operate for the mentally disabled. Saddled with thousands of applications for outpatient programs, there will likely be a delay in approval as the State will have to process these applications and plan for inspections and re-certifications accordingly. Delay in approval will hinder the PPS's ability to implement the vital components of the Project.

Response to waiver request:

**Denied.** OPWDD can provide an operating certificate for up to three years. This cannot be waived because MHL 16.05(f) allows operating certificates to be valid for up to 3 years. It should also be noted that, while we can waive certain elements of regulations governing the CON process, we cannot eliminate the review of projects involving construction. MHL 16.09 requires OPWDD prior approval of construction projects. Also, federal rules preclude Medicaid funding of off-site clinic services that are billed as a clinic service.

**16.12 Stony Brook University Hospital 3.a.i, 4.a.ii 14 NYCRR 620.7; 14 NYCRR 620.9;  
14 NYCRR 620.10 Certification of Need For Administrative Review**

Background and justification provided in your request:

- 14 NYCRR 620.7 regulates the requirements for submitting an application for certification of need for a new program or construction.
- 14 NYCRR 620.9 regulates the review of certification of need application for administrative review projects such as the expansion or contraction of specific services currently offered, an increase or decrease in certified capacity of an existing program, and the acquisition, construction, or capital expenditure for physical plant and/or equipment/assets in support of an existing program, or a combination thereof, estimated to be under \$600,000 but more than \$30,000.
- 14 NYCRR 620.10 regulates the review of certification of need application for substantive review projects such as those expected to cost \$600,000 or more and projects which exceed current certified capacity by 10 percent or 5 persons, whichever is greater.

The referenced regulations interfere with the proposed operation and stated goals of the Projects by imposing the necessity of an administrative and/or substantial review by OPWDD for the provision of primary care, mental and behavioral health services in Article 16-licensed facilities. Such applications of review will likely be submitted by several other PPSs resulting in a delay in approval, and ultimately a delay in the provision of services.

Response to waiver request:

**OPWDD-Approved.** Waiver will be granted subject to the following requirements. Mental and Behavioral Health services provided at the A16 clinic are within authorized billing limits or the provider seeks an increase in the authorized limits.

**OPWDD-Billing- Denied.** Federal rules preclude Medicaid funding of off-site clinic services that are billed as a clinic service, therefore services cannot be delivered in other facilities subject to OPWDD certification.

#### **16.13 Stony Brook University Hospital 4.a.ii 14 NYCRR 810.8; 14 NYCRR 810.9 OASAS- Establishment, Incorporation, Certification Of Providers etc.**

Background and justification provided in your request:

- 14 NYCRR 810.8 regulates the full review process for projects proscribed under 14 NYCRR 810.5, including establishment of any service by a prospective provider that has not been previously certified by OASAS to provide substance use disorder services. Full review requires OASAS review for completeness, local government unit review, and review and recommendation from the Behavioral Health Services Advisory Council (Advisory Council).
- 14 NYCRR 810.9 regulates the administrative review process for projects proscribed under 14 NYCRR 810.6, including establishment or operation of a new service by an existing provider of certified services, an increase in the capacity of a service, and the relocation of any certified service.

The referenced regulations interfere with the proposed operation and stated goals of 4.a.ii by imposing the necessity of a full and/or administrative review by OASAS for the provision of substance use disorder services by a mental provider and the addition of new services administered by OASAS providers. Several tiers of review will likely cause a delay in the provision of services. Additionally, the imposition of conditional certification and periodic

inspections, pursuant to 14 NYCRR 810.13 and 810.14, may cause an interruption in the provision of services and adversely affect the quality of care.

Response to waiver request:

**Integrated services.** Approved solely with respect to 14 NYCRR 599.4(r) and (ab), which will be waived contingent upon following the 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.

#### **16.14 Stony Brook University Hospital 4.a.ii 14 NYCRR 822-4.9; 14 NYCRR 822-5.18 OASAS-Additional Locations for Chemical Dependent Outpatient**

Background and justification provided in your request:

- 14 NYCRR 822-4.9 regulates the provision of chemical dependence outpatient treatment services at additional locations which are dependent upon and subordinate to the main location of the provider. The provider of services must submit an application for additional locations which must be approved pursuant to 14 NYCRR 810 and comply with proscribed space and care protocols.
- 14 NYCRR 822-5.18 regulates the provision of opioid treatment services at additional locations which are dependent upon and subordinate to the main location of the provider. The additional locations must have adequate space and may not exceed 100 additional patients.

The referenced regulations interfere with the proposed operation and stated goals of 4.a.ii by restricting the establishment of additional locations for drug treatment programs to only those locations which are dependent upon and subordinate to the main location of the provider. Satellite OASAS locations, as proscribed in 14 NYCRR 810, have strict requirements that are difficult to meet and will create significant burden on PCP practices, threatening the sustainability of these Projects.

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.

**OASAS response.** Integration solely with respect to 822-4.9 approvable on a case-by-case basis. OASAS requests additional information identifying all providers, services and locations involved.

**OASAS Response.** Solely with respect to 822-5.18 – **Denial.** OASAS does not currently have any certified additional locations for Opioid Treatment services. This provision is being removed from the regulations in 2015.

### **16.15 Stony Brook University Hospital 3.a.i 10 NYCRR 401.1 Department -Issuance of Operating Certificates**

Background and justification provided in your request:

10 NYCRR 401.1 regulates the issuance of operating certificates for new facilities, including clinical treatment programs which provide medical services, other than health monitoring and health screening, that comprise more than five percent of total annual visits, as defined by 14 NYCRR 599. The referenced regulation interferes with the proposed operation and stated goals of 3.a.i by imposing an administrative burden on behavioral health providers to satisfy the operational and economic elements necessary for issuance of a Certificate from the Department. As behavioral health providers are already subject to similar requirements imposed by OMH, duplicative requirements imposes an unnecessary burden and threaten the sustainability of this Project.

Response to waiver request:

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

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

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

### **16.16 Stony Brook University Hospital 3.a.i, 4.a.ii 10 NYCRR 83.5; 10 NYCRR 83.10 Registration of Shared Health Facilities and Shared Health Fac. etc.**

Background and justification provided in your request:

- 10 NYCRR 83.5 regulates the registration of shared health facilities which is effective for a period up to two years and includes specification of the kinds of medical care, services or supplied may be provided.
- 10 NYCRR 83.10 regulates the establishment and maintenance of reports and internal utilization review audits which must be made available from time to time.

The referenced regulations interfere with the proposed operation and stated goals of 3.a.i and 4.a.ii by imposing a burden on primary care and behavioral health providers to register as a shared facility every two years, at minimum; as DSRIP is a five-year program, the PPS will have the administrative burden to apply for subsequent renewal. Further, the Department may verify the application for registration by conducting an on-site visit and interviews, at its discretion. Moreover, the facility must maintain and make available records in addition to any reports already generated. Such audit and investigation will hinder the provision of care by causing unnecessary delays and deter providers from participating in integrated care settings, threatening the sustainability of these Projects.

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.

### **16.17 Stony Brook University Hospital 3.a.i, 4.a.ii 10 NYCRR 83.19 General Structural Equipment and Safety Standards for Shared Health Facilities**

Background and justification provided in your request:

10 NYCRR 83.19 regulates the general structural equipment and safety standards for shared health facilities, including the required parameters for office space, public areas, clinical facilities, and diagnostic facilities. The referenced regulation interferes with the proposed operation and stated goals of 3ai and 4aii, imposing more stringent Department space and facility requirements on mental and behavioral health providers. As a result of the comparably more stringent Department requirements, the capital cost for mental and behavioral health providers will rise as they will be required to renovate their facilities to comply.

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.

**16.18 Stony Brook University Hospital 3.a.i, 4.a.ii 14 NYCRR 814.7 OASAS-General Facility Requirements**

Background and justification provided in your request:

14 NYCRR 814.7 regulates the general facility requirements for shared facilities, mandating providers sharing space to develop a written space use policy or plan in co-operation with such other entity. The referenced regulation interferes with the proposed operation and stated goals of 3.a.i and 4.a.ii, imposing an additional requirement for development of a written plan which is duplicative of the written plan that may be submitted to the Department, OMH, and OASAS, which is compliant with federal rules.

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.

**16.19 Stony Brook University Hospital 3.a.i, 4.a.ii 10 NYCRR 401.2; 10 NYCRR 401.3 Department -Limitations of Operating Certificates/Chgs in Existing Med. Fac.**

Background and justification provided in your request:

- 10 NYCRR 401.2 regulates limitations of Certificates including limiting usage of the Certificate by the established operator of the site.
- 10 NYCRR 401.3 regulates changes in existing medical facilities including prohibiting the operator of a medical facility from leasing or subletting all or a portion of the facility, unless such facility and service performed complied with other medical facility provisions.

The referenced regulations interfere with the proposed operation and stated goals of 3.a.i and 4.a.ii by hindering the sharing of a facility by multiple providers as only the established operator of the facility may use the Certificate. Further, as may be necessary to incent various providers to deliver care in a shared setting, the operator is prohibited from leasing or subleasing space. Such regulations directly conflict with the proliferation of an integrated delivery system and deter achievement of the goals of DSRIP.

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.

#### **16.20 Stony Brook University Hospital 2.b.ix, 3.a.i 10 NYCRR 709.1; 10 NYCRR 709.2 Department -Determination of Public Need for Medical Facility Construction**

Background and justification provided in your request:

- 10 NYCRR 709.1 regulates the process of evaluation to determine public need, pursuant to section 2802 of the Public Health Law. Several factors related to the needs and effects on the population in a specific geographic area are considered prior to approval for an application for public need.
- 10 NYCRR 709.2 regulates the determination of public need for establishment of new/replacement beds in an acute care hospital and the need for acute care facilities/services which entails assessment of geographic needs and population, utilization rates, and types of beds needed.

The referenced regulations impose the administrative burden of seeking approval for construction and addition of bed capacity, pursuant to an evaluation of public need. Approval is at the discretion of an agency that will likely receive an influx of similar applications from other PPSs, delaying the process. The assessment for public need would also be duplicative as the PPS has already conducted a Community Needs Assessment, the results of which were utilized in selection of the Projects.

Response to waiver request:

**Public Need and Financial Feasibility. Approved.** CON review for public need will be waived, with the following qualifications:

- Bed & service reductions still require notification of change through NYSE-CON
- Bed increases in hospitals and nursing homes will remain subject to review for public need and financial feasibility, but will be processed through CON administrative review rather than full review.
- Only the public need and financial feasibility component of the CON process may be waived. Construction standards will not be waived and construction application will still need to be filed through NYSE-CON.
- No waiver is available for specialized services (cardiac surgery, transplants, etc.), CHHA service area expansions, or hospital and nursing home bed increases.
- No waiver is available for establishment applications.

#### **16.21 Stony Brook University Hospital 2.a.i 10 NYCRR 600.1(b)(1) & (b)(3), 600.2(b)(1) & (b)(3) Department -Establishment of new medical facility**

Background and justification provided in your request:

This regulation sets forth the information to be contained within any application to the Public Health Council for the establishment of a new medical facility. Denial of this waiver request would significantly delay the construction process, and affect the speed at which the PPS will be able to achieve the metrics associated with this project. Denial of the waiver would impede the closure of existing gaps in the care continuum, and result in the continuance of inefficient care with respect to areas where the existing medical facilities do not have the systems in place to triage ED patients or redirect them to urgent care, primary care, and/or behavioral health in lieu of ED usage.

Response to waiver request:

**Establishment Action. Denied.** Although review of CON public need and financial feasibility may be waived, CON review of establishment actions will not be granted. All DSRIP projects will be expedited.

#### **16.22 Stony Brook University Hospital 2.a.i 10 NYCRR 670.1 Department -Factors for determining public need for new medical facility**

Background and justification provided in your request:

This regulation sets forth the factors for determining the public need for the establishment of a new medical facility. Denial of this waiver request would significantly delay the construction process, and affect the speed at which the PPS will be able to achieve the metrics associated with this project. Denial of the waiver would impede the closure of existing gaps in the care continuum, and result in the continuance of inefficient care with respect to areas where the existing medical facilities do not have the systems in place to triage ED patients or redirect them to urgent care, primary care, and/or behavioral health in lieu of ED usage.

Response to waiver request:

**Public Need and Financial Feasibility. Approved.** CON review for public need will be waived, with the following qualifications:

- Bed & service reductions still require notification of change through NYSE-CON
- Bed increases in hospitals and nursing homes will remain subject to review for public need and financial feasibility, but will be processed through CON administrative review rather than full review.
- Only the public need and financial feasibility component of the CON process may be waived. Construction standards will not be waived, and construction applications will still need to be filed through NYSE-CON.
- No waiver is available for specialized services (cardiac surgery, transplants, etc.), CHHA service area expansions, or hospital and nursing home bed increases.
- No waiver is available for establishment applications.
- All DSRIP CON applications will be expedited.

#### **16.23 Stony Brook University Hospital 2.a.i, 2.b.ix, 3.a.i, 4.a.ii 10 NYCRR 710.2; 10 NYCRR 710.11 Department -Approval of Medical Facility Construction**

Background and justification provided in your request:

- 10 NYCRR 710.2 regulates the approval process for an application to alter, improve, or modify a medical facility. This includes proposals requiring a certificate of need application such as addition of a licensed service and addition/replacement proposals involving a total project cost in excess of \$6 million; proposals requiring full review and have a project cost in excess of \$15 million; and proposals eligible for administrative review such as the addition/modification/change in the method of delivery of a licensed service, modification of information systems, and the addition of primary care sites.
- 10 NYCRR 710.11 regulates the schedule for construction applications for the review of project scope and concept construction applications by the health systems agencies, the Department, and PHHPC.

The referenced regulations interfere with the proposed operation and stated goals of 2.a.i, 2.b.ix, and 3.a.i by requiring the PPS to submit applications for each Project component that requires Department approval for construction/modification and subscribe to the established application review schedules. The State will receive similar applications from other PPSs, resulting in a delay in approval and ultimately, the failure in achieving Project metrics in Year 1.

Response to waiver request:

**Public Need and Financial Feasibility. Approved.** CON review for public need will be waived, with the following qualifications:

- Bed & service reductions still require notification of change through NYSE-CON
- Bed increases in hospitals and nursing homes will remain subject to review for public need and financial feasibility, but will be processed through CON administrative review rather than full review.
- Only the public need and financial feasibility component of the CON process may be waived. Construction standards will not be waived, and construction applications will still need to be filed through NYSE-CON.
- No waiver is available for specialized services (cardiac surgery, transplants, etc.), CHHA service area expansions, or hospital and nursing home bed increases.
- No waiver is available for establishment applications.
- All DSRIP CON applications will be expedited.

**16.24 Stony Brook University Hospital 2.b.ix, 3.a.i, 4.a.ii 10 NYCRR 712-2.4; 10 NYCRR 715.2.4 Standards of Construction For General Hospital Facilities**

Background and justification provided in your request:

- 10 NYCRR 712-2.4 regulates general hospital construction projects approved or completed after January 1, 2011 that includes approval by the Department for modifications or deletions in space requirements when services are permitted to be shared.
- 10 NYCRR 715-2.4 regulates standards of construction for freestanding ambulatory care facilities after December 31, 2010 that includes Department approval for appropriate deletions and modifications in space and equipment requirements may be made to avoid duplication, when services are shared or purchased.

The referenced regulations interfere with the proposed operation and stated goals of 2.b.ix, 3.a.i and 4.a.ii by requiring the PPS submit separate applications in order to seek waiver

from the construction and design requirements imposed by the Department. Given the short timeframe between the submission and approval of the DSRIP Project Plan application and commencement of Year 1, preparation of submission of several separate applications will impose a significant burden on the PPS as well as the Department, who must approve each submission.

Response to waiver request:

**Construction Standards. Denied.** Due to patient safety concerns, construction regulations cannot be waived. However, the Department will expedite the review of projects associated with DSRIP Project Plans to the extent possible.

**16.25 Stony Brook University Hospital 3.a.i, 4.a.ii 14 NYCRR 814.2; 14 NYCRR 814.3; 14 NYCRR 814.6; 14 NYCRR 814.8; OASAS- General Facility Requirements**

Background and justification provided in your request:

- 14 NYCRR 814.2 regulates the building code requirements for facilities providing OASAS facilities.
- 14 NYCRR 814.3 regulates requirements for all facilities such as floor plan and general building parameters.
- 14 NYCRR 814.6 regulates additional requirements for all outpatient facilities including a waiting area, appropriate to the type of certified service and space for provision of services.
- 14 NYCRR 814.8 regulates space alterations to physical space utilized for chemical dependence services, including requests for additional space, changes in space designations and/or other alterations, which requires prior written approval from OASAS.

The referenced regulations interfere with the proposed operation and stated goals of 3.a.i and 4.a.ii by requiring the PPS submit separate applications in order to seek waiver from the construction and design requirements imposed by the OASAS. Given the short timeframe between the submission and approval of the DSRIP Project Plan application and commencement of Year 1, preparation of submission of several separate applications will impose a significant burden on the PPS as well as OASAS, who must approve each submission.

Response to waiver request:

**More information needed.** OASAS seeks additional information clarifying the proposal. Please provide such information to Trishia Allen of OASAS via email at [Trishia.Allen@oasas.ny.gov](mailto:Trishia.Allen@oasas.ny.gov).

**16.26 Stony Brook University Hospital 3.a.i, 4.a.ii 14 NYCRR 77.2; 14 NYCRR 77.7; 14 NYCRR 77.10 Standards for Physical Facilities of Hospitals etc.**

Background and justification provided in your request:

- 14 NYCRR 77.2 regulates the site and space utilization plan that must be prepared and maintained by each hospital for the mentally ill, school for the mentally retarded and alcoholism facility.

- 14 NYCRR 77.7 regulates design and space requirements for all facilities including parameters for living unit and office spaces.
- 14 NYCRR 77.10 regulates design and space requirements for alcoholism facilities including parameters for interview, examination, and treatments rooms.

The referenced regulations interfere with the proposed operation and stated goals of 3.a.i and 4.a.ii by requiring the PPS submit separate applications in order to seek waiver from the construction and design requirements imposed by the OASAS. Given the short timeframe between the submission and approval of the DSRIP Project Plan application and commencement of Year 1, preparation of submission of several separate applications will impose a significant burden on the PPS as well as OASAS, who must approve each submission.

Response to waiver request:

**Construction Standards. Denied.** Due to patient safety concerns, construction regulations cannot be waived. However, the Department will expedite the review of projects associated with DSRIP Project Plans to the extent possible.

**16.27 Stony Brook University Hospital 2.b.ix, 3.a.i, 4.a.ii 10 NYCRR 710.9  
Department -Approval of Medical Facility Construction**

Background and justification provided in your request:

10 NYCRR 710.9 regulates on-site inspection or pre-opening survey of projects requiring Department approval before an operating certificate may be issued or occupation of the facility. The referenced regulation interferes with the proposed operation and stated goals of 2.b.ix, 3.a.i and 4.a.ii by requiring that a pre-opening survey be conducted before a facility may be occupied, and if applicable, prior to issuance of an operating certificate. Given the short timeframe between the submission and approval of the DSRIP Project Plan application and commencement of Year 1, there will likely be a flux in inspections for facilities as a result of DSRIP causing delays, which ultimately will interfere with the PPSs ability to meet Project metrics for Year 1.

Response to waiver request:

**Pre-Opening Surveys. Denied.** The PPS requested waivers of 10 NYCRR § 701.9, 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.

**16.28 Stony Brook University Hospital 2.a.i Policy that prohibits Medicaid beneficiaries from participating in HH and MLTC plans simultaneously**

Background and justification provided in your request:

Under this policy, Medicaid patients cannot be members of both a Health Home and a Managed Long Term Care Plan. Thus, waiver of this policy is necessary to provide more integrated care to the Medicaid population and will assist the PPS in meeting its goal of shifting care from hospitals to community providers.

Response to waiver request:

**Denied.** Federal requirements do not all allow two case management services at same time.

**16.29 Stony Brook University Hospital 2.a.i, 2.b.iv Policy that denies care in Transitional Care Units to Medicaid beneficiaries**

Background and justification provided in your request:

Section 2802-a of the PHL defines transitional care units as sub-acute care services provided to patients of a general hospital who no longer require acute care general hospital inpatient services, but continue to need specialized medical, nursing and other hospital ancillary services and are not yet appropriate for discharge. Stays are limited in duration and designed to resolve a patient's sub-acute care medical problems and result in the timely and appropriate discharge of such a patient to a home, residential health care facility or other appropriate setting. Thus, waiver of this policy is necessary to provide transitional care services to the Medicaid population.

Response to waiver request:

**More information is needed.** Please provide significant clarification regarding this regulatory waiver request as it is unclear what is being sought and the associated justification.

**16.30 Stony Brook University Hospital 2.b.iv 10 NYCRR 405.9(f)(7) General Hospital Discharges**

Background and justification provided in your request:

10 NYCRR 405.9(f)(7) regulates hospitals to ensure that no person presented for medical care shall be removed, transferred or discharged from a hospital based upon source of payment. The referenced regulation interferes with the proposed operation and stated goals of 2.b.iv as source of payment may be interpreted as applying to DSRIP funding and could prevent a hospital from transferring a patient to the appropriate location. Accordingly, a waiver of the regulation is required to permit successful Project implementation and achievement of Project objectives. Without such a waiver, successful Project implementation will not be feasible.

Response to waiver request:

**Admission, Transfer and Discharge. No waiver needed.** 10 NYCRR § 405.9(f)(7), 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. 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.

**16.31 Stony Brook University Hospital 2.a.i, 2.b.iv 18 NYCRR § 505.10 Prior authorization for non-emergency transportation services**

Background and justification provided in your request:

This regulation requires that prior authorization for non-emergency transportation services be granted prior to transportation expenses being incurred. Waiver of the regulation would make utilization of non-emergency transportation services easier for Medicaid

beneficiaries and will lead to a more integrated and accessible care delivery system under 2.a.i and to fewer 30-day readmissions under 2.b.iv.

Response to waiver request:

**Waiver for transportation prior authorization. Denied** as it could jeopardize the strict financial and programmatic controls in place by the State through its contracted transportation manager.

### **16.32 Stony Brook University Hospital 2.b.ix 10 NYCRR 405.19(g) Emergency Services**

Background and justification provided in your request:

10 NYCRR 405.19(g) regulates hospital observation units for the provision of emergency services including physical space and staffing requirements. Such units may be used only for observation, diagnosis and stabilization of those patients for whom diagnosis and a determination concerning admission, discharge, or transfer cannot be accomplished within eight hours, but can reasonably be expected within 24 hours. The referenced regulation interferes with the proposed operation and stated goals of the 2.b.ix by limiting the amount of time a patient may be in observation and the number of observation beds to five percent of a hospital's certified bed capacity, requiring distinct space and approval for construction of such units. Accordingly, a waiver of the regulation is required to permit successful Project implementation and achievement of Project objectives. Without such a waiver, successful Project implementation will not be feasible.

Response to waiver request:

**Observation Beds-number of 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.

**Observation Beds-length of stay in unit. Approved.** We will waive 405.19 to allow observation unit stay to 48 hours.

### **16.33 Stony Brook University Hospital 2.b.ix 14 NYCRR 580.4 Operation Of Psychiatric Inpatient Units Of General Hospitals**

Background and justification provided in your request:

14 NYCRR 580.4 regulates the issuance of an operating certificate for a general hospital that intends to operate a psychiatric inpatient unit, which is valid for a period not to exceed three years. The referenced regulation interferes with the proposed operation and stated goals of 2.b.ix by requiring the application for an operating certificate by OMH to provide in-patient psychiatric services. OMH will likely receive a large amount of applications from PPSs throughout the State, resulting in a delay in issuance and ultimately, delay of the achievement of Project metrics in Year 1. Given the limited availability of CPEP available in the Suffolk County area, provision of psychiatric observational services by hospitals other than SBUH within the PPS are necessary to address the needs of the attributed Medicaid population.

Response to waiver request:

**OMH Public Need and Financial Feasibility. Approved.** A site-specific project application will still need to be submitted and reviewed by OMH for a determination of

character/competency and/or any environmental review, but will the provider will not need to satisfy a determination of public need nor financial feasibility.

#### **16.34 Stony Brook University Hospital 2.b.ix 14 NYCRR 590.5 Operation of Comprehensive Psychiatric Emergency Program (CPEP)**

Background and justification provided in your request:

14 NYCRR 590.5 regulates the issuance of an operating certificate for a general hospital that intends to operate a CPEP. General hospitals must demonstrate public need, a willingness to serve ethnic minorities, poor and medically indigent patients, and comply with physical plant requirements. The availability of extended observation beds assist in easing inappropriate and often short-term, in-patient admissions. The most recent statewide review of CPEP programs found that only 27 percent of the patients admitted to extended observation beds were hospitalized after their stays. Many patients in the Suffolk County area are in need of short-term stays, less than the 72-hour period proscribed by MHL 9.40, for psychiatric care and do not need to be admitted as an in-patient, however, CPEP capacity across the county is lacking. OMH will likely receiving similar applications for operating certificates to establish CPEP units from other PPSs, resulting in a delay in issuance and ultimately, the PPS's failure to meet Project metrics by Year 1.

Response to waiver request:

**More information needed.** CPEP extended observation beds are acute care services, typically reimbursed at the same per diem rate as an inpatient bed. Expanding this capacity does not appear consistent with the DSRIP aim of decreasing reliance on the most acute services. Rather, OMH would recommend consideration for expansion/implementation of new intensive crisis services. OMH would consider support for an increase in short-term CPEP beds, if that were to enable a decrease in longer stay admissions. Please contact Keith.McCarthy of OMH via email at [Keith.McCarthy@omh.ny.gov](mailto:Keith.McCarthy@omh.ny.gov).

#### **16.35 Stony Brook University Hospital 3.a.i, 4.a.ii 14 NYCRR 599.17(b) Telepsychiatry Services**

Background and justification provided in your request:

14 NYCRR 599.17(b) states that telepsychiatry services must be administered where both the recipient and the physician or nurse practitioner are physically located at [OMH licensed] clinic sites. Provision of such services must be approved by the OMH, which requires the submission of a written plan to the Field Office, who may make an on-site visit prior to issuing approval. The referenced regulation interferes with the proposed operation and stated goals of 3.a.i and 4.a.ii by limiting a provider's ability to provide telepsychiatry services to patients located at sites other than those licensed as clinics by OMH, such as their homes. Further, this regulation imposes the burden to submit a written plan and seek approval by a Field Office prior to the rendering of care. Field Offices will likely be inundated with plans and request for approval from other PPS's, and subsequent need for inspection, which may result in a delay in issuing such approval. Delay in approval will hinder the PPS's ability to implement vital components of the Projects and result in poor health outcomes of the attributed Medicaid population.

Response to waiver request:

**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, and specify why this particular provision may prevent them from proceeding with their desired project. Please contact Keith.McCarthy of OMH via email at [Keith.McCarthy@omh.ny.gov](mailto:Keith.McCarthy@omh.ny.gov)

**16.36 Stony Brook University Hospital 2.a.i 10 NYCRR 415.3(d)(1); 10 NYCRR 751.9(n); 10 NYCRR 763.2(a)(10); 10 NYCRR 766.1(a)(11); 794.1(a) (10**

Background and justification provided in your request:

- 10 NYCRR 415.3(d)(1) states a nursing home resident's right to approve/refuse the release of health records to any individual outside the facility.
- 10 NYCRR 751.9(n) states a D&TC patient's right approve or refuse the release/disclosure of the contents of medical records to any practitioner and/or facility.
- 10 NYCRR 763.2(a)(10) states a CHHA, LTC, or Home Care patient's right to refuse release of records to any individual outside the agency.
- 10 NYCRR 766.1(a)(11) states licensed home care agency patient's right to refuse release of records to any individual outside the agency.
- 10 NYCRR 794.1(a)(10) states a hospice patient's right to refuse release of records to any individual outside the facility.

The referenced regulations interfere with the proposed operation and stated goals of the 2.a.i by serving as an impediment to the process of PHI sharing by imposing administrative hurdles that are unnecessary to maintain the confidentiality of such information. This burden is then transferred to the patient who must opt-in to a function (i.e., information sharing) that is crucial to their long-term care. In order to proactively manage overall health outcomes, it is imperative for PHI to be housed on a secure platform from which providers may analyze and evaluate such PHI to determine the best care and delivery methodologies for each patient individually. The necessity to obtain consent from the patient to authorize PHI sharing with new providers from time to time is unnecessarily duplicative and will likely lead to inefficiencies in care.

Response to waiver request:

**Denied.** This regulation cannot be waived as the patient would have to consent.

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](mailto: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.

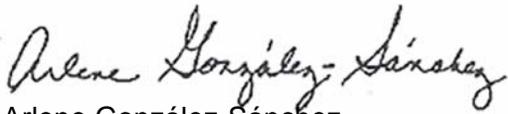
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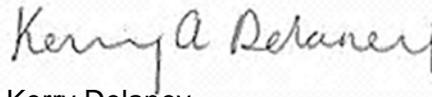
Howard Zucker, M.D., J.D.  
Acting Commissioner  
New York State Department of Health



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



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