



Department  
of Health

Office of  
Mental Health

Office of Alcoholism and  
Substance Abuse Services

March 9, 2015

United Health Services Hospitals, Inc.  
UNITED HEALTH SERV HOSP INC  
Robin Kinslow-Evans, VP Strategic Planning  
10-42 Mitchell Avenue  
Binghamton, NY 13903

Dear Ms. Kinslow-Evans:

The Department of Health (DOH), the Office of Mental Health (OMH), the Office of Alcoholism and Substance Abuse Services (OASAS) are pleased to respond to the request for waivers from certain regulatory requirements submitted under the Delivery System Reform Incentive Payment (DSRIP) Program. This letter responds to the request submitted by United Health Services Hospital in its capacity as lead for the United Health Services Hospitals, Inc. 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, DOH, OMH, and OASAS may waive regulations for the purpose of allowing applicants to avoid duplication of requirements and to allow the efficient implementation of the proposed projects. However, the agencies may not waive regulations pertaining to patient safety nor waive regulations if such waiver would risk patient safety. Further, any waivers approved under this authority may not exceed the life of the project or such shorter time periods as the authorizing commissioner may determine.

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

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

Specific requests for regulatory waivers included in the United Health Services Hospitals, Inc. PPS Project Plan application are addressed below.

**44.01 UHS 2.a.i.; 2.b.iv.; 2.b.vii.; 2.c.i.; 2.d.i.; 3.a.i.; 3.a.ii.; 3.b.i.; 3.g.i.; 4.a.iii.; and 4.b.ii PHL 29F and proposed regulations**

Background and justification provided in your request: The regulatory relief requested is approval of Certificate of Public Advantage (COPA) pursuant to PHL 29F and in accordance with newly promulgated regulations. The projects requested for are: 2.a.i.; 2.b.iv.; 2.b.vii.; 2.c.i.; 2.d.i.; 3.a.i.; 3.a.ii.; 3.b.i.; 3.g.i.; 4.a.iii.; and 4.b.ii. as the components of the various projects require creation of a clinically integrated delivery system and collaborations among providers which may impact market share and competition through a coordinated plan to promote efficiencies and reduce cost of health care delivery. The PPS requires broad state action immunity antitrust protection in order to implement the project requirements imposed by the state.

Response to waiver request:

**No waiver needed.** The regulations have been approved and are in effect.

**44.02 UHS 2.a.i.; 2.b.iv.; 2.b.vii.; 2.c.i.; 2.d.i.; 3.a.i.; 3.a.ii.; 3.b.i.; 3.g.i.; 4.a.iii.and 4.b.ii. 10 NYCRR 405.1 (c)**

Background and justification provided in your request: The regulation requested for waiver is 10 NYCRR 405.1 (c). The projects requested for are: 2.a.i.; 2.b.iv.; 2.b.vii.; 2.c.i.; 2.d.i.; 3.a.i.; 3.a.ii.; 3.b.i.; 3.g.i.; 4.a.iii.and 4.b.ii. to exempt the PPS/Newco from the requirement of becoming an established operator as it carries out its role in governing the PPS, creating collaborative arrangements and approving protocols that impact the delivery of services.

Response to waiver request:

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

**44.03 UHS 2.a.i.; 2.b.iv.; 2.b.vii.; 2.c.i.; 2.d.i.; 3.a.i.; 3.a.ii.; 3.b.i.; 3.g.i.; 4.a.iii. and 4.b.ii. 10 NYCRR 600.9**

Background and justification provided in your request: The regulation requested for waiver is 10 NYCRR 600.9. The projects requested for are: 2.a.i.; 2.b.iv.; 2.b.vii.; 2.c.i.; 2.d.i.; 3.a.i.; 3.a.ii.; 3.b.i.; 3.g.i.; 4.a.iii. and 4.b.ii. to exempt the PPS/Newco from the requirement of becoming an established operator as it carries out its role in governing the PPS, creating collaborative arrangements and approving protocols that impact the delivery of services.

Response to waiver request:

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

**44.04 UHS 2.a.i.; 2.b.iv.; 2.b.vii., 2.c.i.; 2.d.i.; 3.a.i.; 3.a.ii.; 3.b.i.; 3.g.i.; 4.a.iii. and 4.b.ii  
10 NYCRR 600.9 (c)**

Background and justification provided in your request: The regulation requested for waiver is 10 NYCRR 600.9 (c). The projects requested for are: 2.a.i.; 2.b.iv.; 2.b.vii., 2.c.i.; 2.d.i.; 3.a.i.; 3.a.ii.; 3.b.i.; 3.g.i.; 4.a.iii. and 4.b.ii to ensure that the aspects of DSRIP activities which involve distribution of revenue and collaborative arrangement among providers does not violate this regulation which prohibits regulated entities from fee-splitting or sharing in gross revenues of non-established entities. This has been identified as a potential impediment to the flow of funds through the PPS as part of the DSRIP project and a waiver is requested with respect to the financial components of any agreements or other processes providing for the flow of funds with non-established operators since the PPS, Newco and Partner Organizations, may share in distribution of DSRIP funding as part of sharing a patient population and participating in the DSRIP projects. It is important to distinguish this in a manner that it does not constitute illegal fee-splitting with non-established providers.

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.

**44.05 UHS**

Background and justification provided in your request:

The prohibition on the corporate practice of medicine may raise a concern since corporations may not employ licensed professionals to practice medicine, and accordingly, while not a regulatory waiver request, we request DOH to acknowledge, in consultation with Department of Education, that PPS activities do not constitute the corporate practice of medicine under Educ. Law 6522 which provides that only a person licensed or otherwise authorized under Education Law shall practice medicine and 6527 which provides that a non-profit medical or dental expense indemnity corporation or a hospital service corporation may employ licensed physicians. DOH and Department of Education should determine that PPS activities do not constitute the corporate practice of medicine.

All projects are requested for waiver since the PPS and partner organizations will need to enter into collaborative arrangements with physicians to implement PPS-approved care protocols and referral practices.

Response to waiver request:

**Corporate Practice of Medicine. Denied.** The PPS requested regulatory waivers in connection with the corporate practice of medicine, which is a statutory doctrine and therefore

cannot be waived. This request is therefore denied. Please note, however, that the provision of health care services by an Accountable Care Organization (ACO) shall not be considered the practice of a profession under Education Law Title 8, and a PPS may submit an application for an ACO certificate of authority. See 10 NYCRR § 1003.14(f);

[http://www.health.ny.gov/health\\_care/medicaid/redesign/aco/docs/faqs.pdf](http://www.health.ny.gov/health_care/medicaid/redesign/aco/docs/faqs.pdf)

**44.06 UHS 2.a.i.; 2.b.iv.; 2.b.vii.; 2.c.i.; 2.d.i.; 3.a.i.; 3.a.ii.; 3.b.i.; 3.g.i.; 4.a.iii. and 4.b.ii. (HIT) 10 NYCRR 401.3 (a)**

Background and justification provided in your request: The regulation requested for waiver is 10 NYCRR 401.3 (a). The projects requested for are: 2.a.i.; 2.b.iv.; 2.b.vii.; 2.c.i.; 2.d.i.; 3.a.i.; 3.a.ii.; 3.b.i.; 3.g.i.; 4.a.iii. and 4.b.ii. to facilitate rapid implementation in preparation for commencing DSRIP Y1, as all partner organizations and Newco must be in a position to make rapid changes in HIT. All of these projects require the expanded use of HIT technologies and interoperability, which will require investment in new EHR technologies, outlay of capital and the provision of vendor services. The reasons for the waiver request are to relieve the PPS and all partners from seeking further review or approval from the DOH regarding HIT acquisition, installation, modification or outlay of capital to implement necessary technology advances to participate in DSRIP projects.

Response to waiver request:

**HIT Standards. Approved.** The PPS requested a waiver pertaining to CON review of Health Information Technology (HIT) changes in existing medical facilities. A waiver 10 NYCRR § 710.1(b) is approved to waive the financial review however DOH must review each project on a case by case basis to ensure IT standards are met. The PPS should contact DOH's Office of Health Information Technology (OHIT) for approval. To do so, please contact: [SHIN-NY@health.ny.gov](mailto:SHIN-NY@health.ny.gov).

**44.07 UHS 2.a.i.; 2.b.iv.; 2.b.vii.; 2.c.i.; 2.d.i.; 3.a.i.; 3.a.ii.; 3.b.i.; 3.g.i.; 4.a.iii. and 4.b.ii. (HIT) 10 NYCRR 710.1 (c) (2), (3)(i)(j and q), (5) (iv)(g)**

Background and justification provided in your request: The regulation requested for waiver is 10 NYCRR 710.1 (c) (2), (3)(i)(j and q), (5) (iv)(g). The projects requested for are: 2.a.i.; 2.b.iv.; 2.b.vii.; 2.c.i.; 2.d.i.; 3.a.i.; 3.a.ii.; 3.b.i.; 3.g.i.; 4.a.iii. and 4.b.ii. to facilitate rapid implementation in preparation for commencing DSRIP Y1, as all partner organizations and Newco must be in a position to make rapid changes in HIT. All of these projects require the expanded use of HIT technologies and interoperability, which will require investment in new EHR technologies, outlay of capital and the provision of vendor services. The reasons for the waiver request are to relieve the PPS and all partners from seeking further review or approval from the DOH regarding HIT acquisition, installation, modification or outlay of capital to implement necessary technology advances to participate in DSRIP projects.

Response to waiver request:

**HIT Standards. Approved.** The PPS requested waivers of 10 NYCRR § 710.1(b), pertaining to CON review of Health Information Technology (HIT) changes in existing medical facilities. The waiver request is approved to waive the financial review however DOH must review each

project on a case by case basis to ensure IT standards are met. The PPS should contact DOH's Office of Health Information Technology (OHIT) for approval. To do so, please contact: [SHIN-NY@health.ny.gov](mailto:SHIN-NY@health.ny.gov).

#### **44.08 UHS 3.a.i., 3.a.ii., 3.g.i. and 4.a.iii 10 NYCRR 401.3 (a and e)**

Background and justification provided in your request: The projects requested are for: 3.a.i., 3.a.ii., 3.g.i. and 4.a.iii, and may be supplemented as project teams work on implementation design plans, to facilitate the addition or expansion of services and capacity to meet DSRIP goals.

The reason for the waiver requested is to enable the PPS to promote rapid system reconfiguration for implementation of these projects as envisioned in the DSRIP projects submitted, to transform the delivery of services to be integrated and collaborative and expand the ability to meet patient needs in alternative locations such in primary care sites and elsewhere in the community to reduce the reliance on ED and inpatient hospital care. All of these projects require the expansion of capacity or adding or changing existing services, including also relocating services, in some respect by partners implementing the projects. Projects 3.a.ii. and 4.a.iii. for example are aimed to expand the ability to meet the needs of patients in a more comprehensive and collaborative manner so that medical and behavioral care needs are assessed and treated with streamlined access and by implementing collaborative methods including but not limited to IMPACT. The addition of services and capacity may be by primary care and/or behavioral health providers, as determined by whether they pursue implementation through a single provider approach or by co-locating and integrating with other licensed providers in shared space. Project 3.a.i. will require increasing or adding crisis mobilization and stabilization services and locating the provision of such services in alternate locations in the community. Project 3.g.i. will require adding palliative care services in primary care sites and this will expand the capacity of the primary care providers to care for more patients and will expand the scope of services to include palliative care through partnerships with other providers, including Hospice providers. The request for waiver is to relieve the requirements of the need for new CONs and application of assessing need methodology for determination of public need and prior review and approval and in the alternative, for DOH to determine that these elements of the required determinations, review and approval have been satisfied upon approval of the DSRIP Project application and upon PPS notice to DOH of such changes in capacity and service prior to implementation.

Response to waiver request:

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

#### **44.09 UHS 3.a.i., 3.a.ii., 3.g.i. and 4.a.iii 10 NYCRR 670.1 (a-c)**

Background and justification provided in your request: The regulation requested for waiver is 10 NYCRR 670.1 (a-c).

The projects requested for are: 3.a.i., 3.a.ii., 3.g.i. and 4.a.iii, and may be supplemented as project teams work on implementation design plans, to facilitate the addition or expansion of services and capacity to meet DSRIP goals. The reason for the waiver requested is to enable the PPS to promote rapid system reconfiguration for implementation of these projects as envisioned in the DSRIP projects submitted, to transform the delivery of services to be integrated and collaborative and expand the ability to meet patient needs in alternative locations such in primary care sites and elsewhere in the community to reduce the reliance on ED and inpatient hospital care. All of these projects require the expansion of capacity or adding or changing existing services in some respect by partners implementing the projects. Projects 3.a.ii. and 4.a.iii. for e.g. are aimed to expand the ability to meet the needs of patients in a more comprehensive and collaborative manner so that medical and behavioral care needs are assessed and treated with streamlined access and by implementing collaborative methods including but not limited to IMPACT. The addition of services and capacity may be by primary care and/or behavioral health providers, as determined by whether they pursue implementation through a single provider approach or by co-locating and integrating with other licensed providers in shared space. Project 3.a.i. will require increasing or adding crisis mobilization and stabilization services and locating the provision of such services in alternate locations in the community. Project 3.g.i. will require adding palliative care services in primary care sites and this will expand the capacity of the primary care providers to care for more patients and will expand the scope of services to include palliative care through partnerships with other providers, including Hospice providers. The request for waiver is to relieve the requirements of the need for new CONs and application of assessing need methodology for determination of public need and prior review and approval and in the alternative, for DOH to determine that these elements of the required determinations, review and approval have been satisfied upon approval of the DSRIP Project application and upon PPS notice to DOH of such changes in capacity and service prior to implementation.

Response to waiver request:

**Public Need and Financial Feasibility. Approved.** The PPS requested a waiver 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 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.

#### **44.10 UHS 3.a.i.; 3.a.ii.; 3.g.i. and 4.a.iii 10 NYCRR 710.1 (c) (1-5,7)**

Background and justification provided in your request: The regulation requested for waiver is 10 NYCRR 710.1 (c) (1-5,7). The projects requested for are: 3.a.i.; 3.a.ii.; 3.g.i. and 4.a.iii, and may be supplemented as project teams work on implementation design plans, to facilitate the addition or expansion of services and capacity to meet DSRIP goals. The reason for the waiver requested is to enable the PPS to promote rapid system reconfiguration for implementation of these projects as envisioned in the DSRIP projects submitted, to transform the delivery of services to be integrated and collaborative and expand the ability to meet patient needs in alternative locations such in primary care sites and elsewhere in the community to reduce the

reliance on ED and inpatient hospital care. All of these projects require the expansion of capacity or adding or changing existing services in some respect by partners implementing the projects. Projects 3.a.ii. and 4.a.iii. for e.g. are aimed to expand the ability to meet the needs of patients in a more comprehensive and collaborative manner so that medical and behavioral care needs are assessed and treated with streamlined access and by implementing collaborative methods including but not limited to IMPACT. The addition of services and capacity may be by primary care and/or behavioral health providers, as determined by whether they pursue implementation through a single provider approach or by co-locating and integrating with other licensed providers in shared space. Project 3.a.i. will require increasing or adding crisis mobilization and stabilization services and locating the provision of such services in alternate locations in the community. Project 3.g.i. will require adding palliative care services in primary care sites and this will expand the capacity of the primary care providers to care for more patients and will expand the scope of services to include palliative care through partnerships with other providers, including Hospice providers. The request for waiver is to relieve the requirements of the need for new CONs and prior review and approval and in the alternative, for DOH to determine that these elements of the required determinations, review and approval have been satisfied upon approval of the DSRIP Project application and upon PPS notice to DOH of such changes in capacity and service prior to implementation.

Response to waiver request:

**Bed Capacity. Approved.** The PPS requested a waiver of 10 NYCRR §§ 710, pertaining to the CON process for changes in bed capacity. These requests are approved, provided that submission of information through NYSE-CON is necessary for decreases in bed capacity and administrative review necessary for increases in bed capacity. DOH will expedite all DSRIP projects.

#### **44.10 UHS 2.a.i.; 2.b.iv.; 3.a.i.; 3.a.ii.; 3.a.i.; 3.g.i. and 4.a.iii. 10 NYCRR 401.2 (b)**

Background and justification provided in your request: The projects requested for are: 2.a.i.; 2.b.iv.; 3.a.i.; 3.a.ii.; 3.a.i.; 3.g.i. and 4.a.iii.; and may be supplemented as project teams work on implementation design plans, to permit: (1) behavioral and/or substance use providers to operate primary care under the oversight of their regulatory agency in place of DOH and waive adherence to DOH facility standards; (2) Article 28 providers to operate primary care at additional locations within space of a different provider who is separately licensed by a state agency and (3) Article 28 staff to conduct home visits with a site of service in the patient's home. It is a priority to restructure in a way which integrates primary care, behavioral health and/or substance use services and one option is through a single provider with a single licensing agency and another is through integration and co-location of non-Article 28 medical providers or OMH-licensed behavioral and/or substance use providers with Article 28 providers. All of these projects may require changes in the location of existing services to reduce the reliance on hospital-based Emergency Departments and inpatient hospital care in some respect which may be accomplished through the relocation or addition of more locations of services by Article 28-licensed providers to off campus locations. The request for waiver is to permit approval by DOH in the form of approval of the DSRIP project application for relocation or additional locations to sites other than the currently designated site with no further CON required. Waiver will enable the PPS to promote rapid system reconfiguration for implementation of these projects as envisioned in the DSRIP projects submitted. The reason to authorize patients' homes as a site of service eligible for the provision of care and reimbursement is that in order to promote mental health services and reduce the reliance on ED and inpatient use, innovative methods of

ensuring that patients receive necessary treatment will be implemented. The PPS will work with service providers and community based organizations to reduce barriers to access and this may necessitate patients being evaluated and treated in their residence.

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 DOH. DOH will explore, through Value-based Payment options, incorporating more flexibility for home visits, telemedicine and team visits.

#### **44.11 UHS 3.a.i.; 3.a.ii.; 3.g.i. and 4.a.iii 10 NYCRR 710.1(c)(iv)(4)**

Background and justification provided in your request: The regulation requested for waiver is 10 NYCRR 710.1(c)(iv)(4). The projects requested for are: 3.a.i.; 3.a.ii.; 3.g.i. and 4.a.iii, and may be supplemented as project teams work on implementation design plans, to facilitate the relocation of services by waiving prior approval. All of these projects may require changes in the location of existing services to reduce the reliance on hospital-based Emergency Departments and inpatient hospital care in some respect which may be accomplished through the addition, reconfiguration, or relocation of services by Article 28-licensed providers. The request for waiver is to waive any prior review approval and permit letter notification only to DOH only with DOH approval within 15 days. The reason for the waiver requested is to enable the PPS to promote rapid system reconfiguration for implementation of these projects as envisioned in the DSRIP projects submitted.

Response to waiver request:

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

#### **44.12 UHS 2.a.i.; 3.a.i.; 3.g.i. and 4.a.iii 14 NYCRR 600.2**

Background and justification provided in your request: The regulation requested for waiver is 14 NYCRR 600.2. The projects requested for are: 2.a.i.; 3.a.i.; 3.g.i. and 4.a.iii., and may be supplemented as project teams work on implementation design plans, to permit behavioral and/or substance use providers to operate primary care under the oversight of the agency regulating them (OMH, OASAS or OPWDD) without the requirement of DOH approval. One of main priorities of accomplishing DSRIP objectives is to transform the care to patients by restructuring in a way which integrates primary care, behavioral health and/or substance use services and this may be most efficiently accomplished through a single provider with single licensing agency at certain sites of service. We seek to remove or limit impediments to the

provision of integrated services by licensed providers who seek to expand their scope of services.

Response to waiver request:

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

#### **44.13 UHS 2.a.i.; 3.a.i.; 3.g.i. and 4.a.iii 10 NYCRR 401**

Background and justification provided in your request: The regulation requested for waiver is 10 NYCRR 401.3 (d). The projects requested for are: 2.a.i.; 3.a.i.; 3.g.i. and 4.a.iii, and may be supplemented as project teams work on implementation design plans, to permit integration of non-Article 28 medical providers (such as physicians in private practice) or OMH-licensed behavioral and/or substance use providers within the space of an Article 28 and to authorize the Article 28 provider to lease Article 28-approved space to a provider licensed by another State agency without meeting requirements of 10 NYCRR 401.1 et seq. The reason for the request is that the focus of DSRIP is on developing integrated delivery systems, particularly addressing integration of behavioral health, substance use and medical care, and palliative care, must remove or limit impediments to the co-location of services to support implementation of DSRIP integrated care project and redirect some patients away from the ED and reduce hospital admissions through availability of primary and secondary care. One of main priorities of accomplishing DSRIP objectives is to transform the care to patients by restructuring in a way which integrates primary care, behavioral health and/or substance use services and this may be most efficiently accomplished through locating providers in shared space within certain sites of service. We seek to remove or limit impediments to the provision of integrated services by licensed providers who seek to locate their services within Article 28 space under appropriate leasing arrangements.

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. DOH, 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 DOH, 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.

#### **44.14 UHS 2.a.i., 3.a.i., 3.g.i. and 4.a.iii 14 NYCRR 599.4 (ab)**

Background and justification provided in your request: The regulation requested for waiver is 14 NYCRR 599.4 (ab). The projects requested for are: 2.a.i., 3.a.i., 3.g.i. and 4.a.iii., and may be supplemented as project teams work on implementation design plans, to permit Article 28 licensed providers to operate mental health services either within the general hospital or in an outpatient hospital department in amounts which exceed the current limits of visits annually. The 14 NYCRR 599.4 (ab) limits for volume of annual visits which may prevent a provider from qualifying for exemption, for purposes of DSRIP integrated service projects, should be increased from the current limits (10,000 and 2,000) for annual visits to eliminate an annual cap, to exempt the requirement for OMH certification in order to promote the integration of care as part of DSRIP projects. This exemption from requiring OMH licensure, regardless of the number of patients served, will help transform the method of delivering services and increase access to behavioral health and primary 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. DOH, 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 DOH, 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.

#### **44.15 UHS 2.a.i; 3.a.i.; 3.g.i. and 4.a.iii. 14 NYCRR 85.4**

Background and justification provided in your request: The regulation requested for waiver is 14 NYCRR 85.4. The projects requested for are: 2.a.i; 3.a.i.; 3.g.i. and 4.a.iii., and may be supplemented as project teams work on implementation design plans, to permit DOH-regulated providers to operate mental health services under the oversight of the agency regulating them (DOH) and to forgo the requirements of an operating certification from OMH. One of main priorities of accomplishing DSRIP objectives is to transform the care to patients by restructuring in a way which integrates primary care, behavioral health and/or substance use services and this may be most efficiently accomplished through a single provider with single licensing agency at certain sites of service. We seek to remove or limit impediments to the provision of integrated services by licensed providers who seek to expand their scope of services to promote an integrated care model.

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. DOH, 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 DOH, 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.

#### **44.16 UHS 2.a.i; 3.a.i.; 3.g.i. and 4.a.iii. 14 NYCRR § 814.7**

Background and justification provided in your request: The regulation requested for waiver is 14 NYCRR 814.7. The projects requested for are: 2.a.i; 3.a.i.; 3.g.i. and 4.a.iii., and may be supplemented as project teams work on implementation design plans, to permit partner organizations who locate services in shared space with OASAS providers flexibility in the physical requirements of the space provided that the requirements of the federal regulations are adhered to. One of the main priorities of accomplishing DSRIP objectives is to transform the care to patients by restructuring in a way which integrates primary care, behavioral health with substance use. In order to collaborate and integrate, the OASAS providers need to have flexibility to collaborate with other providers in their space and treatment activities. We seek to remove or limit impediments to the provision of integrated services by licensed providers who seek to promote an integrated care model.

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. DOH, 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 DOH, 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.

#### **44.17 UHS 2.a.i.; 3.a.i.; 3.g.i. and 4.a.iii. 10 NYCRR 83.2(a)**

Background and justification provided in your request: The regulation requested for waiver is 10 NYCRR 83.2 (a).

The projects requested for are: 2.a.i.; 3.a.i.; 3.g.i. and 4.a.iii., and may be supplemented as project teams work on implementation design plans, to request waiver of being considered a

Shared Health Facility under 10 NYCRR 83.2(a) and to eliminate need for registration under 10 NYCRR 83.4 and 83.5 and compliance with any requirements of Part 83.

Waiver of this regulatory definitional standard will permit integration of medical providers, behavioral and substance use providers in same settings to promote access to patient. Focus of DSRIP on developing integrated delivery systems, particularly addressing integration of behavioral health, substance use, medical care, and palliative care, so key to remove or limit impediments to the co-location of services to support implementation of DSRIP integrated care projects.

Response to waiver request:

**Denied.** COPA is based in statute, which we do not have the authority to waive.

#### **44.18 UHS 2.a.i and 2.b.iv. 10 NYCRR 405.19 (g) (2,5(b))**

Background and justification provided in your request: The regulation requested for waiver is 10 NYCRR 405.19 (g) (2,5 (b)). The projects requested for are: 2.a.i and 2.b.iv., and may be supplemented as project teams work on implementation design plans, to increase the number of hospital observations beds for the addition of observation unit beds without prior review under section 10 NYCRR 710.1(c)(2) or (3), regardless of project cost and to waive the applicable provisions of Parts 711 and 712-2 and section 712-2.4 of 10 NYCRR for construction projects approved or completed after January 1, 2011 and to waive the physical space and location requirements applicable to placement of observation beds. In order to reduce the rate of hospital admission and facilitate the proper assessment and treatment of patients who may be able to be cared for in the community, or in accordance with a care transitions program, returned to a community setting following a short stay in the hospital as an outpatient, providers will need to expand capacity of observation beds and to have flexibility in the location of the beds.

Response to waiver request:

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

#### **44.19 UHS 14 NYCRR Parts 822 and 841**

Background and justification provided in your request: This request is for DOH to work with CMS through a plan amendment to move OASAS services to the rehabilitation option of the State Medicaid Plan to permit Medicaid reimbursement off site providers to provide home visits. Once OASAS is authorized, we will request waiver relevant sections in 14 NYCRR Parts 822 and 841 to request OASAS to authorize home visits for substance use treatment.

Response to waiver request:

**OASAS- Approved.** Such approval is 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 being pursued by OASAS.

**44.20 UHS 2.b.iv.; 2.b.vii.; and 3.a.ii., 10 NYCRR 405.9 (b)(2) and (f)(7)**

Background and justification provided in your request: The regulation requested for waiver is 10 NYCRR 405.9 (b)(2) and (f)(7). The projects requested for are: 2.b.iv.; 2.b.vii.; and 3.a.ii., and may be supplemented as project teams work on implementation design plans, to permit providers when making admission decisions and when conducting discharge planning and placement of Medicaid and Uninsured to implement PPS-approved protocols for care transitions and care pathways, protocols to manage patients in appropriate settings and implement project goals to reduce ED and inpatient hospital usage.

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.

**44.21 UHS 2.a.i.; 2.b.iv.; 2.b.vii.; 2.c.i.; 2.d.i.; 3.a.i; 3.a.ii.; 3.b.i.; 3.g.i.; 4.a.ii. and 4.b.iii. 10 NYCRR Part 405; specifically 405.2(e)(3) and §405.4(c)(5)**

Background and justification provided in your request: The regulations requested for waiver are: 10 NYCRR Part 405; specifically 405.2 (e)(3) and §405.4(c)(5). The projects requested for are: 2.a.i.; 2.b.iv.; 2.b.vii.; 2.c.i.; 2.d.i.; 3.a.i; 3.a.ii.; 3.b.i.; 3.g.i.; 4.a.ii. and 4.b.iii. to streamline the credentialing process within the PPS to create a system-wide process which will facilitate the rapid integration of services required to provide coordinated care by providers participating in PPS. In particular, the waiver would allow PPS to establish a shared credentialing process and standards to: (i) conduct primary source verification; (ii) screen for Medicare and Medicaid exclusion; (iii) and assure consistent standards to promote quality and patient safety, relying on data available to partner organizations and to the PPS through its own monitoring and data collection. The waiver would reduce the cost and administrative burden of credentialing by each partner organization, and would allow health care professionals to practice in different settings as needed for care coordination without duplicative credentialing by numerous providers throughout the PPS. The waiver is also requested to permit certain practices that may be necessary to implement coordinated care models, such as allowing a physician in private practice to supervise more than two physicians' assistants (10 NYCRR 94.2).

Response to waiver request:

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

**44.22 UHS 2.a.i.; 2.b.iv.; 2.b.vii.; 3.a.ii.; and 4.a.iii 10 NYCRR Part 415.39(a-e)**

Background and justification provided in your request: This request is to waive regulations encompassed by 10 NYCRR Part 415.39(a-e) that govern the provision of behavioral health services by skilled nursing facilities (SNFs). The projects requested for are: 2.a.i.; 2.b.iv.; 2.b.vii.; 3.a.ii.; and 4.a.iii, and may be supplemented as project teams work on implementation design plans, to authorize the provision of expanded behavioral health services, as appropriate, at skilled nursing facilities to reduce preventable hospital use in the emergency room and preventable hospital admissions. The waiver is requested to allow SNFs to admit a higher number of patients with behavioral health conditions, and care for them with access to the necessary expertise and physician supervision through telemedicine and increased affiliations with partner organizations, in accordance with the policies and procedures adopted by the SNFs and the PPS to assure patient safety of both the residents treated and other residents in the facilities. Specifically, PPS is seeking to waive the requirements to: (i) establish or operate an independent unit to treat patients for behavioral health conditions (10 NYCRR 415.39(a)(3); and (ii) allow flexibility to permit therapeutic interventions in the SNFs and provide access to health care professionals from partner organizations in the PPS to expand the availability of expertise and treatment to better manage and care for patients with behavioral health needs in SNFs.

Response to waiver request:

**Waiver not needed.** A waiver is not needed for a nursing home to admit a higher number of patients with behavioral health conditions, and care for them with access to the necessary expertise and physician supervision through telemedicine and increased affiliations with partner organizations, in accordance with the policies and procedures adopted by the SNFs and the PPS to assure patient safety of both the residents treated and other residents in the facilities.

**44.23 UHS 2.a.i.; 2.b.iv.; 3.a.ii.; 3.b.i.; and 4.b.ii. 10 NYCRR §766.4**

Background and justification provided in your request: This request seeks a waiver of 10 NYCRR §766.4 to allow physician assistants to sign medical orders for home care services provided by licensed home care services agencies (LHCSAs). In addition to the specific waiver request above, PPS requests that the Department of Health and Department of Education pursue a legislative proposal to allow non-patient specific nurse-driven protocols by amending the Nurse Practice Act and regulations in Title 8. Additionally, pursue legislative changes to permit home health aides with appropriate training to administer medications in home care and hospice settings, and provide other advanced interventions that are deemed safe and appropriate by the regulators. This would also facilitate system clinical integration and the projects that seek to provide timely preventive and daily care to patients in their homes or other community settings. The projects requested for are: 2.a.i.; 2.b.iv.; 3.a.ii.; 3.b.i.; and 4.b.ii., and may be supplemented as project teams work on implementation design plans, to authorize Physician Assistants (PAs) to issue home care orders and be deemed authorized practitioners under 10 NYCRR §763.7.

Response to waiver request:

**Determination pending.**

**44.24 UHS 2.a.i.; 2.b.iv.; 2.b.vii.; 3.a.i.; and 3.a.ii. 10 NYCRR §400.11(a)**

Background and justification provided in your request: This request is to waive 10 NYCRR §400.11(a), to permit staff who do not satisfy the credentials set forth in the regulations to conduct an assessment necessary for initial or continued placement in a nursing home to perform the assessments. The projects requested for are: 2.a.i.; 2.b.iv.; 2.b.vii.; 3.a.i.; and 3.a.ii., and may be supplemented as project teams work on implementation design plans, to facilitate the transfer of residents from hospitals to nursing homes by allowing health care professionals with a broader range of credentials than those identified in the regulations to conduct the assessment of potential residents prior to their initial or continued placement in long-term care facilities.

Response to waiver request:

**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.

#### **44.25 UHS 2.a.i; 2.b.iv; 2.b.vii; 3.a.i; and 3.a.ii 10 NYCRR §700.3(a)(1-2)**

Background and justification provided in your request: This request is to waive 10 NYCRR §700.3(a)(1-2) to permit staff who do not satisfy the credentials set forth in the regulations to conduct an assessment necessary for initial or continued placement in a nursing home to perform the assessments. The projects requested for are: 2.a.i; 2.b.iv; 2.b.vii; 3.a.i; and 3.a.ii, and may be supplemented as project teams work on implementation design plans, to facilitate the transfer of residents from hospitals to nursing homes by allowing health care professionals with a broader range of credentials than those identified in the regulations to conduct the assessment of potential residents prior to their initial or continued placement in long-term care facilities.

Response to waiver request:

**PRI requirement. Approved.** 10 NYCRR 700.3 requires Hospital/Community PRI or PRI as well as the SCREEN. We cannot waive the SCREEN portion of this regulation or the credentialing requirements for the person who completes the SCREEN as this is a federal requirement. We will waive the PRI requirement in 700.3 provided that the provider notify, and obtain approval from, the department for an alternative screening tool.

#### **44.26 UHS 2.a.i.; 2.b.iv.; 3.a.i.; 3.a.ii. and 4.a.iii 14 NYCRR 679.5**

Background and justification provided in your request: This request is to waive 14 NYCRR 679.5. The projects requested for are: 2.a.i.; 2.b.iv.; 3.a.i.; 3.a.ii. and 4.a.iii, and may be supplemented as project teams work on implementation design plans, to permit to permit clinic treatment staff to conduct home visits and be eligible for reimbursement with a site of service in the patient's home. The reason for this request is that in order to promote mental health services and reduce the reliance on ED and inpatient use, innovative methods of ensuring that patients receive necessary treatment will be implemented. The PPS will work with service providers and community based organizations to reduce barriers to access and this may necessitate patients being evaluated and treated in their residence.

Response to waiver request:

**OMH- denied.**14 NYCRR § 599.14. Per CMS, Medicaid will not reimburse for mental health services provided off-site.

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.

Sincerely,



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



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



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