March 12, 2015

Dave Smingler
Ellis Hospital
ELLIS HOSPITAL / ST PETERS HOSPITAL
1101 Nott Street
Schenectady, New York 12308

Dear Mr. Smingler:

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

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

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

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

Specific requests for regulatory waivers included in the Ellis Hospital PPS Project Plan application are addressed below.

3.01 Ellis Hospital 3ai 10 NY CRR 864.9

Background and justification provided in your request:

The regulation that the Ellis PPS would like waived is 10 NY CRR 864.9. Presently, Article 28 Hospital Outpatient Departments and Diagnostic & Treatment Centers (D&TCs) providers are limited to one threshold visit being billed per patient per day, regardless of the number of clinical interventions being completed on that day in that single site of care.

This waiver is being requested to facilitate the implementation of Project 3.a.i, Integration of Primary Care and Behavioral Health Services. Delivery of Primary Care and Behavioral Health services in the same setting will undoubtedly lead to services from each discipline being provided to a patient on the same day in order to maximize the integration of Physical and Behavioral Health services. The Ellis PPS believes that to support the integration of care, D&TCs will need to be adequately reimbursed to cover costs.

Response to waiver request:

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

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

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

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

- 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.

3.02 Ellis Hospital

2.a.i The regulations that the PPS seeks waivers on to facilitate the project 2.a.i, Integrated Delivery System, are: CHHA assessments Title 10 NYCRR Part 763.3 and 42 CFR 484. 55 (federal); Plan of Care: Title 18 NYCRR section 540, Title 10 NYCRR 763.6, 42 CFR 484.18 (federal); Physician Orders: Title 10 NYCRR 766.4, Title 10 NYCRR 763.7.

Background and justification provided in your request:

These regulations are duplicative of MLTC requirements. The IDS should be integrated to the degree that its assessments are not duplicative and such a system would have efficient, necessary and timely changes in a care plan. The ease of service changes within the IDS plan of care should not be hindered by duplicative assessments.

This waiver will assist in reach project goals by making the process more efficient. It will help build relationship of confidence with a singular care coordinator who is not leading a patient through unnecessary burdensome steps, it will make for faster decisions and it will save system resources. Using the MLTC UAS system, is consistent with the direction of the NYS Medicaid program.

Response to waiver request:

CHHA assessments Title 10 NYCRR Part 763.3 and 42 CFR 484. 55 (federal) Denied. The State and federal regulations (ex-OASIS assessment) require a comprehensive assessment of prospective home health agency patients. We do not have the authority to waive federal requirements. The UAS cannot be used in lieu of the federal OASIS assessment, as the assessments contain different information.

Plan of Care: Title 18 NYCRR section 540, Title 10 NYCRR 763.6, 42 CFR 484.18 (federal). Denied. The State regulations mirror the federal requirements. We do not have the authority to waive federal requirements.

Physician Orders: Title 10 NYCRR 766.4, Title 10 NYCRR 763.7. Determination pending.

3.03 Ellis Hospital 2.a.i Title 10 NYCRR, 415.26 and 400.11 - project 2.a.i

Background and justification provided in your request:

The waiver of these regulations would facilitate the implementation of project 2.a.i, Integrated Delivery System. The PPS seeks to allow a Nursing Home to admit someone without requiring a PRI and Screen, to enable more rapid admission. The movements of patients within the PPS should be timely yet considered. Care planning within an IDS for a patient based on the right care, in the right place at the right time should not be delayed due to a PRI or a Screen. The purpose of these forms has changed over time but their use now is to ensure that an improper placement doesn't take place; that responsibility will be passed to the IDS, making these forms redundant.

Also, in rural or border communities where the local hospital is out of state (Hoosick Falls as an example in this DSRIP region), arranging for a person trained to conduct these evaluations can delay admission. This waiver will allow the PPS to base admission planning on the IDS systems

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 process and/or tool.

3.04 Ellis Hospital 2.a.i Title 18 NYCRR, 540.6

Background and justification provided in your request:

This request pertains to Project 2.a.i, Integrated Delivery System- it seeks to establish an exception to the 90-day time limitation for Medicaid billing. All too often the delays in doctors turn-around of written orders go past the 90-day limit, due to the limits of physician turn-around in signing orders. There are often patients treated with verbal physician orders but not signed orders. Many of these patients end up in cases approaching 90 days from admission and leave the agency without a mechanism for payment and at risk of limiting or eliminating patient access to care. This is especially acute in the urban clinic settings.

The waiver is necessary simply to insure payment for services rendered in a market place where the cost/reimbursement ration is very tight. As the Office of Health Insurance has recognized, this issue is outside of the control of the Home Care agency. This negatively affects patient access to care as agreed upon in concept by the Department of Health. An extension to 180 days for timely billing of Home Care claims is requested.

Response to waiver request:

Waive 90 day billing limitation. More information needed. 10 NYCRR 763.7(a)(3) requires a signed written order within 30 days after admission to a CHHA. The PPS will need to submit a waiver request for both Title 18 NYCRR, 540.6, as well as Title 10 NYCRR 763.7(a)(3), if it is seeking a waiver for the 90 day billing limitation.

3.05 Ellis Hospital 3.a.iv

Background and justification provided in your request:

The Ellis PPS requests a waiver regarding the regulations governing the provision of ancillary withdrawal in 822.4 and 822.5 clinics and the ability to offer voluntary ambulatory detoxification services. This waiver is being requested to facilitate the implementation of Project 3.a.iv, Development of Withdrawal Management Capabilities. The waiver will support the ability of existing withdrawal management providers (Part 816 programs) to operate ambulatory detox programs. Currently, only Part 822.4 and Part 822.5 outpatient OASAS providers can operate ambulatory detox programs connected to their existing outpatient clinic programs. The waiver, if granted, would allow existing Part 816 inpatient detox units to offer ambulatory detox programs leveraging existing staff and expertise, and creating access for members 24/7. In addition, it would help eliminate the need to transfer patients from a Part 822-4 or 822-5 clinic to a Part 816 program for acute management of withdrawal when the patient presents with severe withdrawal or have used substances within the last 24 hours. If the Part 816 program can provide the ambulatory detox, there is a greater continuity of care. If the waiver is granted, Part 816 providers would offer ancillary withdrawal services as an additional level of care to the medically managed and medical supervised withdrawal services they currently offer. Ancillary withdrawal services would be provided consistent with existing OASAS regulations and guidance documents.

The waiver would allow existing inpatient detox programs the ability to provide ambulatory detox services to members presenting for symptom relief in the emergency departments and newly developed ED Triage services. This "no wrong door" approach would expedite the referral of patients to the most appropriate and least restrictive level of care reducing wait times for services with a goal of seamless transitions. As it currently stands, OASAS indicates that Part 822-4 and 822-5 providers should be familiar with Part 816.5 (C) (1)

– Procedures for the clinical evaluation and management of alcohol and/or other substance specific withdrawal syndromes, to include the use of standardized withdrawal evaluation instruments, (including, but not limited to, Clinical Institute Withdrawal Assessment [CIWA] or Clinical Opiate Withdrawal Scale [COWS], if available).

Response to waiver request:

Approvable on a case by case basis. Approvable contingent upon the submission of ambulatory detox protocols to the OASAS Medical Director for review and approval. Please submit such documentation to Trishia Allen of OASAS via email at Trishia.Allen@oasas.ny.gov.

3.06 Ellis Hospital 2.a.i

Background and justification provided in your request:

This waiver would facilitate the implementation of Project 2.a.i, Integrated Delivery System. Various references in the NYS Residential Health Care Code are made regarding allowed and covered services. Many services are not specifically prohibited, but there is no language specifically allowing them (such as chemotherapy services, hyperbaric services for wound care.) An IDS should plan and coordinate services across service lines. Often the reason an SNF resident is admitted to a hospital is based on strict understandings of the limits of SNF care. These limits should be flexible in a changing health system. Avoiding Hospital admissions can be achieved by reconsidering limits on SNF care. A committee of providers and regulators should consider expansion of SNF services and the require audits by the SNF quality programs. The MLTCs would need to approve and properly compensate all providers.

Response to waiver request:

No waiver needed. Current regulations do not specifically address all services such as chemotherapy, hyperbaric services, etc., that can be provided in a Skilled Nursing Facility (SNF). The types of services that can be provided in a SNF are continually changing making it difficult to codify each specific service. However, the SNF must consider the state and federal regulatory requirements that must be met based on the services being provided, such as construction requirements.

3.07 Ellis Hospital 4.a.iii State Plan amendment (in Section 599.14)

Background and justification provided in your request:

The Ellis PPS requests a waiver in the form of a State Plan amendment (in Section 599.14), which currently does not provide reimbursement for collaborative team meetings.

This waiver will facilitate the implementation of Project 4.a.iii, Strengthen Mental Health and Substance Abuse Infrastructure across Systems. The change would enable providers from multiple clinical disciplines to be reimbursed for team meetings for comprehensive care planning (which is currently not billable). These team meetings are an important component proposed within the plans of Project 4.a.iii.

The PPS requests this waiver because section 599.14. This stands in the way of integrating behavioral health and primary care since the two disciplines need to talk but, while the talk in allowed, the professional staff is not willing to do so for free. Integrating Behavioral

Health and other health disciplines creates the opportunity to effectively collaborate. The current system is to schedule separate appointments on separate times and likely places and share notes (at best). The Ellis PPS expects to combine these services by location and need the change in regulations would maximize the benefit.

If the waiver is granted, multidisciplinary providers would be reimbursed for team meetings. The change would make the patient easier to engage in the dual health needs by creating a unified approach toward care.

Response to waiver request:

Approved by OMH. OASAS Response – A SPA is not needed to the extent that the services are provided pursuant to the threshold model, or are provided at an OASAS 822 facility.

3.08 Ellis Hospital 3.a.i

Background and justification provided in your request:

This waiver is being requested to facilitate the implementation of Project 3.a.i, Integration of Primary Care and Behavioral Health Services. Physical location at the same address and use of shared space for primary care and behavioral health services is currently prohibited because of this regulation. The main component of the plans for project 3.a.i is to co-locate PC into BH services and vice versa. Ellis PPS is requesting this waiver in order to facilitate the integration of primary care into currently licensed OMH and OASAS provider spaces.

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.

In cases where waivers are approved, the agencies will send letters directed to the providers which otherwise would be responsible for complying with the regulatory provisions at issue. Providers further will be advised that agency staff who conduct surveillance activities will be notified that these regulatory waivers have been approved; however, they should maintain a copy of their waiver letters at any site subject to surveillance.

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

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

Sincerely,

Howard A. Zueker, 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