



Department
of Health

Office of
Mental Health

Office of Alcoholism and
Substance Abuse Services

March 11, 2015

Richard Cleland, President, C.O.O. & Interim C.E.O.
Millennium Collaborative Care PPS (ECMC)
ERIE COUNTY MEDICAL CTR
462 Grider Street
Buffalo, New York 14215

Dear Mr. Cleland:

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 Erie County Medical Center in its capacity as lead for the Millennium Collaborative Care 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 Millennium PPS Project Plan application are addressed below.

48.01 Millennium Collaborative Care PPS (ECMC) 2.b.vii Determinations of Public Need (10 NYCRR 760.5)

Background and justification provided in your request:

CON waiver expedition in order to establish women’s behavioral health unit at Terrace View/ECMC to decrease hospitalizations for this underserved segment of the population. We have identified a need for a higher level of SNF based behavioral health for women, mirroring a very successful men’s behavioral health unit at Terrace View ECMC. This would cross multiple projects, allowing for most appropriate care for a population that is frequently admitted to the hospital. Requests a waiver of Department regulation (10 NYCRR 760.5 – determination of “need” for a home care agency), stating that they “have identified a need for a higher level of SNF (skilled nursing facility) based behavioral health for women, mirroring a very successful men’s behavioral health unit at Terrace View ECMC.”

Response to waiver request:

OMH – More information needed. The existing initiative referenced (Terrace View) is unknown to OMH; therefore, OMH needs more information relative to that initiative before being able to opine on the project being proposed. OMH needs to better understand ECMC’s overall behavioral health planning moving forward before making a determination on this request. Please submit additional information to Keith McCarthy at OMH via email at Keith.McCarthy@omh.ny.gov

48.02 Millennium Collaborative Care PPS (ECMC) 2.b.viii Determinations of Public Need (10 NYCRR 760.5)

Background and justification provided in your request:

CON waiver expedition for home care agency (CHHA); application to add new services to operating certificate (ECMC) to serve the entire PPS geography. There are very few safety net home care providers, and no CHHA in our PPS. There is great need in the Medicaid and uninsured population for continued skilled services post discharge. Expanding ECMC’s operating certificate to include a CHHA would allow us to continue to treat patients through the entire continuum, at a level of accountability and quality that will allow us to meet all of our metrics.

Response to waiver request:

CHHA-Determination pending.

48.03 Millennium Collaborative Care PPS (ECMC) 2.b.vii Physician Assistants and Nurse Practitioners in SNFs (18 NYCRR, Section 540.6(4))

Background and justification provided in your request:

Implementation of the INTERACT protocol and reducing transfers to the ER/Hospital. Waiver or medication of this regulation would encourage facilities to employ physician assistants and nurse practitioners because it would allow them to keep Medicare Part B offset funds that

would normally be taken away from the Medicaid rate. PAs/NPs would allow the facilities to support an ever increasing acuity of patients and fully operationalize the INTERACT project.

Response to waiver request:

Approved.

48.04 Millennium Collaborative Care PPS (ECMC) 2.b.vii Telemedicine/Telehealth (18 NYCRR Section 505.9)

Background and justification provided in your request:

Implementation of the INTERACT protocol; would allow for practitioners to be reimbursed for communicating via telemedicine with facility staff to avoid hospital transfer via remote consultation. This waiver would allow for specialists to reach a higher volume of patients throughout the day than would normally occur if patients required transportation or the specialist needed to travel between facilities. It would allow for specialists to be reimbursed for this care, lending to system transformation and viability exceeding the five years of DSRIP. Current regulations do not allow telemedicine reimbursement in most circumstances, which impedes the ability of specialists to utilize the efficiency of such a model.

Response to waiver request:

Billing telehealth, practitioner to practitioner interactions- Denied. OHIP will explore in the future.

48.05 Millennium Collaborative Care PPS (ECMC) 2.b.viii Telemedicine/Telehealth (18 NYCRR Section 505.9)

Background and justification provided in your request:

Would allow lower level practitioners and Care transitions specialists to correspond with specialists and PCPs to avoid hospitalizations via remote consultation. This waiver would allow for specialists to reach a higher volume of patients throughout the day than would normally occur if patients required transportation or the specialist needed to travel between facilities. It would allow for specialists to be reimbursed for this care, lending to system transformation and viability exceeding the five years of DSRIP. Current regulations do not allow telemedicine reimbursement in most circumstances, which impedes the ability of specialists to utilize the efficiency of such a model.

Response to waiver request:

Billing telehealth, practitioner to practitioner interactions - Denied. OHIP will explore in the future.

48.06 Millennium Collaborative Care PPS (ECMC) 3.a.ii Telemedicine/Telehealth (18 NYCRR Section 505.9)

Background and justification provided in your request:

Would allow psychiatrists to be reimbursed for remote consultation with patients in the community and in their homes reducing hospital transfers. This waiver would allow for specialists to reach a higher volume of patients throughout the day than would normally occur if patients required transportation or the specialist needed to travel between facilities. It would

allow for specialists to be reimbursed for this care, lending to system transformation and viability exceeding the five years of DSRIP. Current regulations do not allow telemedicine reimbursement in most circumstances, which impedes the ability of specialists to utilize the efficiency of such a 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. 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.

48.07 Millennium Collaborative Care PPS (ECMC) 2.b.iii SNFs and Patient Review Instrument (PRI) (10 NYCRR 400.11 and 10 NYCRR 415.26)

Background and justification provided in your request:

Expedite transfer to SNF from ER to divert hospital admissions for patients with higher acuity but do not require acute care. The PRI requirement as it stands today can prolong admission in the hospital and delay transfer to an SNF. Coordination of appropriate professionals to screen with PRI increases cost and time patients spend in hospital or ER awaiting transfer. Waiving this regulation could allow SNFs to more quickly review a patient and transfer them from the ER or community, reducing hospitalizations.

Response to waiver request:

PRI requirement. Approvable on a case-by-case basis. 10 NYCRR 400.11(a) requires Hospital/Community PRI or PRI as well as the SCREEN. We will waive the PRI requirement in 400.11(a) on a case-by-case basis provided that the provider notify, and obtain approval from, the Department for an alternative screening tool.

SCREEN requirement. Denied. 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.

48.08 Millennium Collaborative Care PPS (ECMC) 2.b.vii SNFs and Patient Review Instrument (PRI) (10 NYCRR 400.11 and 10 NYCRR 415.26)

Background and justification provided in your request:

Would allow SNFs to receive transfers quicker without waiting for qualified PRI screener, could divert ER to hospital secondary to decreasing wait time for transfer. Also expedite the process for SNFs that border Pennsylvania, where PRI screening regulations vary. The PRI requirement as it stands today can prolong admission in the hospital and delay transfer to an

SNF. Coordination of appropriate professionals to screen with PRI increases cost and time patients spend in hospital or ER awaiting transfer. Waiving this regulation could allow SNFs to more quickly review a patient and transfer them from the ER or community, reducing hospitalizations.

Response to waiver request:

PRI requirement. Approvable on a case-by-case basis. 10 NYCRR 400.11(a) requires Hospital/Community PRI or PRI as well as the SCREEN. We will waive the PRI requirement in 400.11(a) on a case-by-case basis provided that the provider notify, and obtain approval from, the Department for an alternative screening tool.

SCREEN requirement. Denied. 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.

48.09 Millennium Collaborative Care PPS (ECMC) 2.b.vii Changes in existing medical facilities (10 NYCRR 401.3 and 10 NYCRR 710)

Background and justification provided in your request:

The application and approval process for changes to existing facilities may need to be waived for implementation of several projects, including 2.b.vii (INTERACT), 2.b.viii (Hospital-Home Care Collaboration) and 3.a.i (Integration of Primary and Behavioral Services). The PPS will develop detailed requests for regulatory waivers as project plans are developed. Plans will ensure that patient safety is considered and addressed in any scenario where a regulatory waiver is sought.

Response to waiver request:

Bed Capacity. Approved. The PPS requested waivers of 10 NYCRR 401.3, and 710 pertaining to the CON process for changes in bed capacity. Regulations requiring that bed capacity increases be subject to a full CON review are waived. These requests are approved, provided that the facility submit a limited review application for decreases in bed capacity and an administrative review application for increases in bed capacity. The Department will expedite all applications related to DSRIP projects.

48.10 Millennium Collaborative Care PPS (ECMC) 2.b.viii Changes in existing medical facilities (10 NYCRR 401.3 and 10 NYCRR 710)

Background and justification provided in your request:

The application and approval process for changes to existing facilities may need to be waived for implementation of several projects, including 2.b.vii (INTERACT), 2.b.viii (Hospital-Home Care Collaboration) and 3.a.i (Integration of Primary and Behavioral Services). The PPS will develop detailed requests for regulatory waivers as project plans are developed. Plans will ensure that patient safety is considered and addressed in any scenario where a regulatory waiver is sought.

Response to waiver request:

Bed Capacity. Approved. The PPS requested waivers of 10 NYCRR 401.3, and 710 pertaining to the CON process for changes in bed capacity. Regulations requiring that bed capacity increases be subject to a full CON review are waived. These requests are approved,

provided that the facility submit a limited review application for decreases in bed capacity and an administrative review application for increases in bed capacity. The Department will expedite all applications related to DSRIP projects.

48.11 Millennium Collaborative Care PPS (ECMC) 3.a.i Changes in existing medical facilities (10 NYCRR 401.3 and 10 NYCRR 710)

Background and justification provided in your request:

The application and approval process for changes to existing facilities may need to be waived for implementation of several projects, including 2.b.vii (INTERACT), 2.b.viii (Hospital-Home Care Collaboration) and 3.a.i (Integration of Primary and Behavioral Services). The PPS will develop detailed requests for regulatory waivers as project plans are developed. Plans will ensure that patient safety is considered and addressed in any scenario where a regulatory waiver is sought.

Response to waiver request:

Bed Capacity. Approved. The PPS requested waivers of 10 NYCRR 401.3, and 710 pertaining to the CON process for changes in bed capacity. Regulations requiring that bed capacity increases be subject to a full CON review are waived.

These requests are approved, provided that the facility submit a limited review application for decreases in bed capacity and an administrative review application for increases in bed capacity. The Department will expedite all applications related to DSRIP projects.

48.12 Millennium Collaborative Care PPS (ECMC) 2.b.vii Certificate of Need regarding establishment (10 NYCRR 405.1, 10 NYCRR 600 and 10 NYCRR 710)

Background and justification provided in your request:

The activities undertaken for these projects could implicate establishment requirements. As project plans are developed in more detail a specific waiver request will be submitted.

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).

48.13 Millennium Collaborative Care PPS (ECMC) 2.b.viii Certificate of Need regarding establishment (10 NYCRR 405.1, 10 NYCRR 600 and 10 NYCRR 710)

Background and justification provided in your request:

The activities undertaken for these projects could implicate establishment requirements. As project plans are developed in more detail a specific waiver request will be submitted.

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).

48.14 Millennium Collaborative Care PPS (ECMC) None Given Management Contracts and Sharing of Revenue (10 NYCRR 405.3 and 10 NYCRR 600.9)

Background and justification provided in your request:

It is anticipated that certain arrangements entered into by PPS hospitals could be deemed “management contracts” requiring prior Department approval. As the intended arrangements are developed specific requests for waiver may be submitted.

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.

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).

Management Contracts. Denied. The PPS requested waivers of 10 NYCRR § 405.3 and 600.9 regarding management contracts. The Department has determined that it will need to review each management contract to ensure that the contracting agency is not acting as a governing body.

48.15 Millennium Collaborative Care PPS (ECMC) 3.a.i Billing (10 NYCRR 86-4.9(b))

Background and justification provided in your request:

To support the integration of primary care and behavioral health, providers may require waiver of regulations that restrict them from generating more than one threshold visit bill per day to support the costs of multiple providers of service. While we acknowledge that these regulations may not be eligible for waiver at this time, we wanted to note the issue.

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.

48.16 Millennium Collaborative Care PPS (ECMC) 2.b.viii Practitioner Home Visits (10 NYCRR 401.1; 10 NYCRR 401.2(b));

Background and justification provided in your request:

Under current regulation operating certificate holders, except in limited circumstances, may not provide services off site, including services at patients' homes. Article 28 hospitals and D&T Centers within the PPS request waiver of applicable regulations to permit home visits for outpatient departments of such Article 28 hospitals and D&T Centers.

Response to waiver request:

Off-Site Services or Home Visits. Approved. The PPS requested waivers of 10 NYCRR § 401.2(b) for the purpose of allowing practitioners affiliated with Article 28 providers to provide services outside of the certified service site. The request is approved, contingent upon notification by the PPS of the specific providers, practitioners and services. However, reimbursement for the provision of such services would not be available absent approval of a State Plan Amendment (SPA) to the State Medicaid Plan and associated state regulations, both of which are being pursued by the Department. The Department will explore, through Value-based Payment options, incorporating more flexibility for home visits, telemedicine and team visits.

48.17 Millennium Collaborative Care PPS (ECMC) Various Restrictions on Part Time Clinics (10 NYCRR 401.1; 10 NYCRR 700.2(a)(22); 10 NYCRR 703.6)

Background and justification provided in your request:

An Article 28 facility providing services off site may only do so in an extension or part time clinic. Part time clinics are limited to low-risk procedures and examinations and may not operate for more than 60 hours per month. The PPS may require flexibility with respect to part time clinics. The scope of the waiver required will become more evident as projects are planned in detailed.

Response to waiver request:

Off-Site Clinics. Approved. Extension clinics may operate for less than 60 hours per month and offer a full complement of services. Review for public need and financial feasibility for CON applications for extension clinics will be waived.

48.18 Millennium Collaborative Care PPS (ECMC) Various Admission, Discharge and Transfer (10 NYCRR Parts 400.9, 400.11 405.9, 415.38 and 700.3; 18 NYCRR 5

Background and justification provided in your request:

As project plans are developed, it is anticipated that the referenced regulations may pose impediments to smooth and rapid transition of patients between care levels. More specific requests for regulatory relief will be submitted once project plans are developed.

Response to waiver request:

Admission, Transfer and Discharge. No waiver needed. The PPS requested waivers of 10 NYCRR Parts 400.9, 400.11 405.9, 415.38 and 700.3; 18 NYCRR 5, 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.

48.19 Millennium Collaborative Care PPS (ECMC) 3.a.ii Observation Services (10 NYCRR 405.19)

Background and justification provided in your request:

It is anticipated that flexibility will be needed for use of observation services in connection with this project, including the physical space requirements and an expansion of the maximum observation unit stay from 24 to 48 hours.

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.

Observation Beds. Approved. We will waive 405.19 to allow observation unit stay to 48 hours.

48.20 Millennium Collaborative Care PPS (ECMC) 2.b.vii Nursing Home Transfers (10 NYCRR 415.3 and 10 NYCRR 415.4)

Background and justification provided in your request:

Regulations that compel nursing homes to transfer patients (in particular behavioral patients) to hospitals to protect the safety of other residents, should be modified or waived to allow for appropriate therapeutic interventions within the nursing home.

Response to waiver request:

Resident rights, Resident behavior and facility practices. More information needed to demonstrate what regulatory barriers exist that prohibit a nursing home from providing appropriate and needed services.

48.21 Millennium Collaborative Care PPS (ECMC) 2.b.viii Home Care Orders by Nurse Practitioners and Physician Assistants (10 NYCRR 763.7)

Background and justification provided in your request:

Home care ordering authority should be broadened to allow for workforce flexibility.

Response to waiver request:

Denied. We do not have the authority to waive a federal requirement.

48.22 Millennium Collaborative Care PPS (ECMC) 2.b.viii Home Health Aide Supervision (10 NYCRR 766.5)

Background and justification provided in your request:

Broader range of clinicians should be able to perform home health aide supervision, including utilizing methods other than on-site supervision.

Response to waiver request:

Waiver not needed. Currently L.P.N.s, R.N.s, and therapists are able to supervise home health aides.

48.23 Millennium Collaborative Care PPS (ECMC) None Given Relocations: 10 NYCRR 708.3. And 708.4 Facility and service changes and closures: 10 NYCRR 401.3(g)

Background and justification provided in your request:

It is anticipated that project plans may involve bed and service relocations between established providers within the PPS as well as closures of services and facilities. The PPS requests that these relocations and closures be permitted upon notification to the Department. Specific requests for waiver will be submitted as plans are further developed.

Response to waiver request:

Bed and Service Relocations. No Waiver Needed. Transfers and relocations of beds and services between general hospitals within an established Article 28 network as defined in 10 NYCRR 401.1 are subject only to limited review, submitted through NYSE-CON.

Facility Closure. Denied. While the Department will expedite approvals of closures, to the extent appropriate for facilitation of the PPS Project Plan, appropriate notice is important to patients/residents, families, vendors, other providers, and communities. Moreover, the Department cannot circumvent federal and state statutory requirements such as the federal Worker Adjustment and Retraining Notification (WARN) Act. The request therefore are denied.

48.24 Millennium Collaborative Care PPS (ECMC) 2.a.i Construction projects 10 NYCRR Part 600.

Background and justification provided in your request:

The PPS requests that the level of CON review for construction related to the above projects be limited to architectural review, with an expedited review process and requests that the PPS be permitted to self-certify for architectural and other code compliance to expedite PPS projects.

Response to waiver request:

Public Need and Financial Feasibility. Approved. The PPS requested waivers with respect to the public need and financial feasibility components of the CON process. Waivers are approved for 10 NYCRR §§ 670.1, 709 and 710.2, however, that:

- No waiver is available for establishment applications.
- Only the public need and financial feasibility components of the CON process are waived, meaning that a construction application still needs 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.

48.25 Millennium Collaborative Care PPS (ECMC) 2.b.iii Construction projects 10 NYCRR Part 600.

Background and justification provided in your request:

The PPS requests that the level of CON review for construction related to the above projects be limited to architectural review, with an expedited review process and requests that the PPS be permitted to self-certify for architectural and other code compliance to expedite PPS projects.

Response to waiver request:

Public Need and Financial Feasibility. Approved. The PPS requested waivers with respect to the public need and financial feasibility components of the CON process. Waivers are approved for 10 NYCRR §§ 670.1, 709 and 710.2, however, that:

- No waiver is available for establishment applications.
- Only the public need and financial feasibility components of the CON process are waived, meaning that a construction application still needs 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.

48.26 Millennium Collaborative Care PPS (ECMC) 2.b.vii Construction projects 10 NYCRR Part 600.

Background and justification provided in your request:

The PPS requests that the level of CON review for construction related to the above projects be limited to architectural review, with an expedited review process and requests that the PPS be permitted to self-certify for architectural and other code compliance to expedite PPS projects.

Response to waiver request:

Public Need and Financial Feasibility. Approved. The PPS requested waivers with respect to the public need and financial feasibility components of the CON process. Waivers are approved for 10 NYCRR §§ 670.1, 709 and 710.2, however, that:

- No waiver is available for establishment applications.
- Only the public need and financial feasibility components of the CON process are waived, meaning that a construction application still needs 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.

48.27 Millennium Collaborative Care PPS (ECMC) 3.a.i Construction projects 10 NYCRR Part 600.

Background and justification provided in your request:

The PPS requests that the level of CON review for construction related to the above projects be limited to architectural review, with an expedited review process and requests that the PPS be permitted to self-certify for architectural and other code compliance to expedite PPS projects.

Response to waiver request:

Public Need and Financial Feasibility. Approved. The PPS requested waivers with respect to the public need and financial feasibility components of the CON process. Waivers are approved for 10 NYCRR §§ 670.1, 709 and 710.2, however, that:

- No waiver is available for establishment applications.
- Only the public need and financial feasibility components of the CON process are waived, meaning that a construction application still needs 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.

48.28 Millennium Collaborative Care PPS (ECMC) 3.a.ii Construction projects 10 NYCRR Part 600.

Background and justification provided in your request:

The PPS requests that the level of CON review for construction related to the above projects be limited to architectural review, with an expedited review process and requests that the PPS be permitted to self-certify for architectural and other code compliance to expedite PPS projects.

Response to waiver request:

Public Need and Financial Feasibility. Approved. The PPS requested waivers with respect to the public need and financial feasibility components of the CON process. Waivers are approved for 10 NYCRR §§ 670.1, 709 and 710.2, however, that:

- No waiver is available for establishment applications.
- Only the public need and financial feasibility components of the CON process are waived, meaning that a construction application still needs 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.

48.29 Millennium Collaborative Care PPS (ECMC) 2.a.i Prohibitions Against Fee-Splitting (10 NYCRR § 600.9).

Background and justification provided in your request:

Regulations prohibiting fee-splitting or -sharing in gross revenues of non-established entities must be waived with respect to the financial components of any agreements dictating

the flow of dollars, such as distribution of DSRIP proceeds among PPS providers sharing a patient population.

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.

48.30 Millennium Collaborative Care PPS (ECMC) 3.a.i Co-location. 10 NYCRR Part 83 (Shared Health Facilities); Shared Space (Two or More Providers) 10

Background and justification provided in your request:

There are a numerous restrictions on co-location and agency approvals required for co-located services that will need to be waived or modified in order to efficiently implement 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.

48.31 Millennium Collaborative Care PPS (ECMC) 3.a.i 14 NYCRR Parts 510 & 520 (accessing or correcting OMH record) 14 NYCRR Parts 803 & 804

Background and justification provided in your request:

There are various regulations that govern and restrict how health and behavioral information can be shared. To effectively integrate behavioral health and physical health services as contemplated by the above projects, patient information must be able to be shared between providers and record-keeping requirements should be uniform so as not to require duplicate efforts.

Response to waiver request:

Sharing of Patient Information. OMH-Denied. Both 14 NYCRR 510 Part 803 (public access to records) and 520 (access to or amendment /correction of records) apply only to providers directly operated by OMH; neither is applicable to licensed community mental health providers. Further, Part 510 reflects the Freedom of Information Law, which cannot be waived. Part 520 also implements a statutory requirement and hence cannot be waived. OMH fails to see the connection between these regulations and the ability to integrate treatment records.

Sharing of Patient Information. OASAS-Denied. Both 14 NYCRR Part 803 (public access to records) and Part 804 (access to information) correlate to statutory requirements, which cannot be waived. Further, neither provision speaks to the ability to integrate treatment records.

48.32 Millennium Collaborative Care PPS (ECMC) 3.a.ii 14 NYCRR Parts 510 & 520 (accessing or correcting OMH record) 14 NYCRR Parts 803 & 804

Background and justification provided in your request:

There are various regulations that govern and restrict how health and behavioral information can be shared. To effectively integrate behavioral health and physical health services as contemplated by the above projects, patient information must be able to be shared between providers and record-keeping requirements should be uniform so as not to require duplicate efforts.

Response to waiver request:

Sharing of Patient Information. OMH-Denied. Both 14 NYCRR 510 Part 803 (public access to records) and 520 (access to or amendment /correction of records) apply only to providers directly operated by OMH; neither is applicable to licensed community mental health providers. Further, Part 510 reflects the Freedom of Information Law, which cannot be waived. Part 520 also implements a statutory requirement and hence cannot be waived. OMH fails to see the connection between these regulations and the ability to integrate treatment records.

Sharing of Patient Information. OASAS-Denied. Both 14 NYCRR Part 803 (public access to records) and Part 804 (access to information) correlate to statutory requirements, which cannot be waived. Further, neither provision speaks to the ability to integrate treatment records

48.33 Millennium Collaborative Care PPS (ECMC) 2.a.i 10 NYCRR §§ 405.9, 400.9, 400.11, 700.3, 415.38, 18 NYCRR §§ 505.20 and 540.5, 14 NYCRR § 36.4 and 1

Background and justification provided in your request:

Currently, various agencies have rules and regulations governing patient transitions. These processes must be waived or streamlined in an integrated environment. The specific waiver needs will become more apparent as project plans are developed.

Response to waiver request:

Request not specific. Additional information needed.

48.34 Millennium Collaborative Care PPS (ECMC) 3.a.i 10 NYCRR §§ 405.9, 400.9, 400.11, 700.3, 415.38, 18 NYCRR §§ 505.20 and 540.5, 14 NYCRR § 36.4 and 1

Background and justification provided in your request:

Currently, various agencies have rules and regulations governing patient transitions. These processes must be waived or streamlined in an integrated environment. The specific waiver needs will become more apparent as project plans are developed.

Response to waiver request:

Please see the response below. If this does not meet your needs, please submit a complete waiver request that contains the waiver being requested with the specific regulation citation, justification, and impact on patient safety.

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.

48.35 Millennium Collaborative Care PPS (ECMC) 3.a.ii 10 NYCRR §§ 405.9, 400.9, 400.11, 700.3, 415.38, 18 NYCRR §§ 505.20 and 540.5, 14 NYCRR § 36.4 and 1

Background and justification provided in your request:

Currently, various agencies have rules and regulations governing patient transitions. These processes must be waived or streamlined in an integrated environment. The specific waiver needs will become more apparent as project plans are developed.

Response to waiver request:

Please see the response below. If this does not meet your needs, please submit a complete waiver request that contains the waiver being requested with the specific regulation citation, justification, and impact on patient safety.

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.

48.36 Millennium Collaborative Care PPS (ECMC) 2.a.i 3 (OASAS Providers) 10 NYCRR Parts 94 and 707, 10 NYCRR § 405.2 a

Background and justification provided in your request:

In order to effectively establish an integrated delivery system, the PPS must implement a uniform credentialing process, which will require waiver or modification of the referenced regulations

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.

OASAS requests additional information from the PPS identifying how the proposed waive would impact OASAS providers.

48.37 Millennium Collaborative Care PPS (ECMC) 3.a.i 14 NYCRR Part 77 (governing physical plant standards for behavioral health facilities)

Background and justification provided in your request:

Integration of behavioral health and primary care under Models A and B may require waiver of some physical standards for behavioral health facilities.

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.

48.38 Millennium Collaborative Care PPS (ECMC) 2.a.i Article 32 Home/Off-Site Visits (14 NYCRR 822 and 14 NYCRR 841)

Background and justification provided in your request:

The PPS hopes to provide engagement and outreach services in the community because many patients fail to receive the care they need. The PPS would like to offer service to patients under Home and Community Based Services-Adult Mental Health to patients eligible for Health and Recovery Plans (HARP).

Response to waiver request:

Off site visits. 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.

48.39 Millennium Collaborative Care PPS (ECMC) 2.b.viii Article 32 Home/Off-Site Visits (14 NYCRR 822 and 14 NYCRR 841)

Background and justification provided in your request:

The PPS hopes to provide engagement and outreach services in the community because many patients fail to receive the care they need. The PPS would like to offer service to patients under Home and Community Based Services-Adult Mental Health to patients eligible for Health and Recovery Plans (HARP).

Response to waiver request:

Off-site visits. 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.

48.40 Millennium Collaborative Care PPS (ECMC) 2.a.i Article 31 and Article 32 Clinic Reimbursement for Primary Care Services

Background and justification provided in your request:

Currently, a provider licensed by OMH under MHL Article 31 to provide outpatient mental health services or certified by OASAS under MHL Article 32 to provide outpatient substance use disorder services must obtain PHL Article 28 licensure by the Department if more than 5 percent of total visits are for primary care services or if any visits are for dental services. We request regulatory changes to facilitate integration of primary care and behavioral health services and simplify the licensure process. Furthermore, we request that primary care is allowed to be provided under Title 14 regulations and payment is allowable regardless of the percent of visits for 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. 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.

48.41 Millennium Collaborative Care PPS (ECMC) 3.a.i Article 31 and Article 32 Clinic Reimbursement for Primary Care Services

Background and justification provided in your request:

Currently, a provider licensed by OMH under MHL Article 31 to provide outpatient mental health services or certified by OASAS under MHL Article 32 to provide outpatient substance use disorder services must obtain PHL Article 28 licensure by the Department if more than 5 percent of total visits are for primary care services or if any visits are for dental services. We request regulatory changes to facilitate integration of primary care and behavioral health services and simplify the licensure process. Furthermore, we request that primary care is allowed to be provided under Title 14 regulations and payment is allowable regardless of the percent of visits for 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. 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.

48.42 Millennium Collaborative Care PPS (ECMC) 2.a.i Limitation on the number of physician assistants a physician may supervise (10 NYCRR 94.2)

Background and justification provided in your request:

To increase capacity of PCPs within the IDS. Data from the CNA clearly indicates inadequacies of PCPs for both medical and especially behavioral health patients. With PCP shortages locally and nationwide and accompanying increase in demand for practitioners at the gate-keeper levels, increase in mid-level providers to accommodate the shortage is inevitable. Without assistance from adequately trained mid-level practitioners, implementation of the project will yield less than optimum results: patients will be disengaged due to long waiting times to see practices (sometimes months), and patients may opt out of the program which will negatively impact the PPS. Follow-up of behavioral health patients from inpatient stays may be impeded due to inadequacy of providers, which may result in readmission within 30 days, thus negatively impacting the project.

Response to waiver request:

Physician assistants. Denied as the limit on the number of physician assistants a physician may supervise is a patient safety protection.

48.43 Millennium Collaborative Care PPS (ECMC) 3.a.ii Limitation on the number of physician assistants a physician may supervise (10 NYCRR 94.2)

Background and justification provided in your request:

To increase capacity of PCPs within the IDS. Data from the CNA clearly indicates inadequacies of PCPs for both medical and especially behavioral health patients. With PCP shortages locally and nationwide and accompanying increase in demand for practitioners at the gate-keeper levels, increase in mid-level providers to accommodate the shortage is inevitable. Without assistance from adequately trained mid-level practitioners, implementation of the project will yield less than optimum results: patients will be disengaged due to long waiting times to see practices (sometime months), and patients may opt out of the program which will negatively impact the PPS. Follow-up of behavioral health patients from inpatient stays may be impeded due to inadequacy of providers, which may result in readmission within 30 days, thus negatively impacting the project.

Response to waiver request:

Physician assistants. Denied. This requirement is based in statute, which we do not have the authority to waive.

48.44 Millennium Collaborative Care PPS (ECMC) 3.b.i Allowance of self-referral for sub specialties such as cardiology/primary care (10 NYCRR 34)

Background and justification provided in your request:

Allowance of self-referral for qualified subspecialties (especially cardiology) would increase patient engagement and adherence, which would positively impact the project. Cardiology subspecialists who provide services for the Medicaid population often prefer to provide cardiology rather than primary care services because of referral regulations and payment structure. This waiver would allow cardiologists to offer both primary care and cardiology services, and physicians will be willing to provide more primary care services. This will reduce the chasm of increasing demand and reducing supply vis-à-vis cardiology, which is a high need for all Medicaid population. This will also enable patients to receive service in a one-stop-shop fashion, which is very helpful especially with difficulties in transportation associated with the Medicaid population. We acknowledge that the practice may implicate federal law as well.

Response to waiver request:

Physician Self-Referral. Denied. This requirement is based in statute, which we do not have the authority to waive.

48.45 Millennium Collaborative Care PPS (ECMC) 2.b.iii Approval of Protocols Article 30, Section 3002-A-2(c)

Background and justification provided in your request:

This article states in part: "The State Emergency Medical Services Advisory Council (SEMAC) shall also review protocols developed by regional emergency medical advisory committees (REMACs) for consistency with statewide standards." The proposed DSRIP program will require protocols that exceed the current state standards (i.e., more correctly viewed as the scope of practice for a paramedic); and, the SEMAC's three meetings or fewer a year are insufficient to meet the quickly evolving needs of this program. Further, SEMAC statewide protocols do not take into account the vastly different types of care that would be delivered by our community paramedics. In fact, it could be argued that treatment of patients in the field by mid-level providers and physicians in the call/coordinating center using telemedicine and community paramedics as proxies is not EMS at all. Modification of the scope of practice

for community paramedics will need to be redefined by the Department. While we acknowledge that these issues do not directly relate to regulations that are eligible for waiver, we wanted to note the issue.

Response to waiver request:

Not applicable as a regulatory waiver was not requested.

48.46 Millennium Collaborative Care PPS (ECMC) 2.b.iii Alternate Site/Transport Methods New York State Basic Life Support (BLS) Protocol

Background and justification provided in your request:

DSRIP agencies may utilize alternate transportation methods and transport destinations based on specially created and regionally approved DSRIP protocols. This will require relief from sections of the current BLS protocols, which limit approved transport methods and transport destinations. We believe that these protocols are less than statutory or regulatory, but will still require some type of relief by the governing body (the Department's Bureau of Emergency Medical Services) and wanted to make note of the issue.

Response to waiver request:

Not applicable as a regulatory waiver was not requested.

48.47 Millennium Collaborative Care PPS (ECMC) 2.b.iii Alternate Site/Transport Methods New York State (BLS) Protocol Reimbursement for Transportation

Background and justification provided in your request:

MA currently only reimburses EMS agencies for care of patients who are transported to a receiving facility. Since the ED Care Triage project will involve treatment by community paramedics without transport and/or transport to a non-traditional facility (perhaps by another non-medical transportation entity such as a cab service), reimbursement for this care by MA is not allowable at this time. While we acknowledge that applicable regulations may not be eligible for waiver, we wanted to note this issue and request relief to allow for payment by MA for care by community paramedics regardless of transport to an approved receiving facility. In addition, we request that MA recognize and provide reimbursement for the mid-level/physician care provided via telemedicine from the call/coordination center using the community paramedic as the hands/eyes/ears of the clinicians (i.e., care proxies).

Response to waiver request:

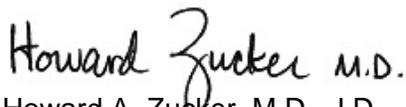
Denied. This would require a change in statute, which we do not have the authority to waive. Public Health Law does not permit community paramedicine and only allows EMS agencies to provide care during an emergency.

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

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

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

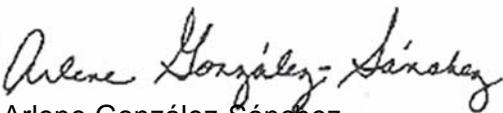
Sincerely,



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



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



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