



Department  
of Health

Office of  
Mental Health

Office of Alcoholism and  
Substance Abuse Services

December 15, 2015

Millennium Collaborative Care PPS  
Erie County Medical Center  
Greg Turner, DSRIP Director  
Millennium Collaborative Care  
462 Grider Street  
Buffalo, New York 14215

Dear Mr. Turner:

The New York State Department of Health (DOH), the Office of Mental Health (OMH), and 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 (PPS).

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

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

**1 Millennium Collaborative Care 709.3 2.a.i.; 2.b.vii.; 3.a.i.**

**Background and Justification submitted with your request:**

In order to further integrate UAHS (by merging Olean General Hospital and Bradford Regional MC), the Sub Acute Rehab program needs to be continued (has \$650K margin). The average daily census of a merged entity would exceed the 100 limit for swing beds. Converting the swing beds to SNF beds addresses the issue as LTC beds are not counted in average daily census. The further integration of UAHS will have a \$1.5M impact on the system, clearly having a stabilizing effect on OGH. The further integration will also assist OGH in projects noted herein.

**Response to Waiver Request:**

**No waiver needed.** There is no regulatory limit on a hospital's swing bed capacity. If the PPS wishes to change the designation of 20 hospital swing beds to nursing home beds, hospital regulations and reimbursement would no longer apply to these beds. Nursing home regulations and reimbursement apply. Bed need methodology aside, the PPS may find that the cost of complying with nursing home requirements (i.e. renovations and space requirements) is too high to be cost effective. The change in reimbursement might also erode some of the current profit margin derived from the swing beds.

**2 Millennium Collaborative Care 10 NYCRR 83 3 fi, 4 di**

**Background and Justification submitted with your request:**

Both organizations already have a good working relationship but realize that the best case scenario would be to co-locate. By doing so both organizations would increase their staff's knowledge, encourage further collaboration, decrease overall costs and expand service provision. Additionally, consumers, and human service agencies, would know where to go for the critical services these programs provide to new moms and children.

**Response to Waiver Request:**

**Determination pending.** The potential for permitting providers to share the same licensed physical space is under review.

**3 Millennium Collaborative Care Sections 2962, 2970, 2971 of PBH Law 2bvii**

**Background and Justification submitted with your request:**

1. Current regulation requires a Physician to sign off on MOLST. This can cause a delay in MOLST activation or providers to be out of compliant. There also exists varying time frames of recertification depending on the patient's setting, such as review every seven days in an acute setting. We request that NPs and Pas be

- allowed to sign these orders so that providers and facilities more easily maintain compliance, and patient orders be activated more timely.
2. Nurse Practitioners and Physician Assistants already engage patients and healthcare decision makers in end-of-life care discussions
  3. NPs and PAs receive training that prepares them to have discussions on the kinds of medical interventions that are discussed on the MOLST form and what those interventions would do for the patient
  4. Sometimes there is a delay in the MOLST process because the form must be signed by both the patient/decision maker and the physician but the physician isn't on site to validate the form
  5. Allowing NPs and PAs to sign the MOLST form to create immediately actionable orders will help to encourage discussion of end-of-life treatment options and raise awareness of the availability of MOLST
  6. Allowing NPs and PAs to sign the MOLST form would ensure patient's end-of-life care preferences are honored by eliminating any delays.

**Response to Waiver Request:**

**Denied.** We do not have the authority to waive state statute.

**4 Millennium Collaborative Care Section 2802-a of PHL amended by Chapter 58 authorizing Commissioner to approve TCUs 2bvii**

**Background and Justification submitted with your request:**

1. Allow Ventilator beds in Transitional Care unit allowing for an average length of stay greater than 20 days. CON would be necessary for the transition of standard TCU beds to ventilator beds. The currently is a great shortage of post-acute ventilator beds in Western New York, with patients being transferred to Pennsylvania and NYC as a result. The addition of these beds would allow us to care for the residents of WNY in their community.
2. Allow TCU to receive Medicaid reimbursement. Currently TCU's cannot receive Medicaid reimbursement. This would limit the patients who may require the higher acuity care that can be provided on a TCU increasing acute LOS or readmissions from SNFs.
3. Allow transfers from other PPS hospitals. Currently the TCU must accept patients from its own hospital where it is located. If these ventilator beds are located in the TCU, it would fill the need from the community and entire PPS. We ask that this waiver not be limited to ventilator beds and allow all TCU beds to accept transfers.
4. Allow an average Length of stay greater than 20 days for ventilator beds. The patients would be located within the hospital in the TCU, which would allow a lengthened weaning potential in the safest environment.

**Response to Waiver Request:**

**Denied.** We do not have the authority to waive state statute.

**5 Millennium Collaborative Care NYCRR Subpart 67-13 2(b)vii**

**Background and Justification submitted with your request:**

Request the use of an EPOC Electronic Point of Care Technology to obtain Blood Chemistry and Hematology within minutes. Requesting that this be added as a CLIA waived service enabling on-the-spot assessment without having to send patients to the E.R. or Hospital for Assessment and appropriate treatment. Obtain “instant” results for specific blood chemistry and hematology to be immediately incorporated into decision to transfer patient to the hospital or treat in place in the SNF.

**Response to Waiver Request:**

**Denied.** We do not have the authority to waive state statute.

**6 Millennium Collaborative Care 10 NYCRR 83 3 fi and 4 di**

**Background and Justification submitted with your request:**

Expansion of obstetrics and reduce low birth rates. Colocation allows for us to operate a site in the same space as the county. Both clinics will operate separate EHRs.

**Response to Waiver Request:**

**Determination pending.** The potential for permitting providers to share the same licensed physical space is under review.

**7 Millennium Collaborative Care 10 NYCRR 401.1, 10 NYCCR 700.2 (a)(22) and 10 NYCRR (703.6) 3 fi and 4 di**

**Background and Justification submitted with your request:**

Expansion of obstetrics and reduce low birth rates. Colocation allows for us to operate a site in the same space as the county. Both clinics will operate separate EHRs.

**Response to Waiver Request:**

**Determination pending.** The potential for permitting providers to share the same licensed physical space is under review.

**8 Millennium Collaborative Care 14 NYCRR 599.4 (r) and (ab) 3 fi and 4 di**

**Background and Justification submitted with your request:**

Expansion of obstetrics and reduce low birth rates. Colocation allows for us to operate a site in the same space as the county. Both clinics will operate separate EHRs.

**Response to Waiver Request:**

**Determination pending.** The potential for permitting providers to share the same licensed physical space is under review.

**9 Millennium Collaborative Care 14 NYCRR 599.4 (r) and (ab) 3 ai**

**Background and Justification submitted with your request:**

Restriction easement on threshold visits allows us to perform services at same time for patient convenience.

**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. However, the Department, OMH and OASAS do not believe any additional waivers are needed if providers are integrating services under such a model. 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; and 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.

**10 Millennium Collaborative Care Title X: Section 709.8 (b)(4) 2.a.i**

**Background and Justification submitted with your request:**

Granting this waiver to reduce the required number of pediatric BMT beds to 2, would allow WCHOB to secure licensed pediatric BMT beds in the Oishei Children's Hospital to optimize delivery of care, keeping patients closer to home and avoiding costly travel or sending patients out of state for services through our collaboration with Roswell Park Cancer Institute. A pediatric BMT program is an essential component of a comprehensive pediatric hematology/oncology program.

**Response to waiver Request:**

**Approved.** BMT Beds.

**11 Millennium Collaborative Care Title X: Section 405.30 (b) (3) 2.a.i**

**Background and Justification submitted with your request:**

When fully operational, to ensure quality of care, the hospital shall perform at least 10 liver transplants per year if it is to continue as an approved liver transplant program; or at least 10 human heart transplants per year if it is to continue as an approved heart transplant program; or at least 10 kidney transplants a year if it is to continue as an approved kidney transplant program; or at least 10 lung transplants per year if it is to continue as an approved lung

transplant program. The Department will monitor outcomes for graft and patient survival. Granting this waiver to reduce the number of pediatric kidney transplants, would allow WCHOB to optimize delivery of pediatric kidney transplant care for our community, as the only stand-alone Children's Hospital allowing us to treat patients closer to home, avoiding costly travel or sending patients out of state for services, through collaboration with Erie County Medical Center.

**Response to waiver Request:**

**More Information needed.** The Department cannot waive the CON requirement for full review of a pediatric transplant program. However, we would consider waiving the programmatic minimum volume requirement in an approved pediatric transplant program.

**12 Millennium Collaborative Care NYS Physical Therapy: Rules & Regulations:  
6738 Ciii (iii) 2.b.viii**

**Background and Justification submitted with your request:**

6738 Ciii (iii) states that periodic treatment and evaluation of the patient by the supervising licensed physical therapist, as indicated in the plan of care and as determined in accordance with patient need, but in no instance shall the interval between such treatment exceed every six patient visits or thirty days, whichever occurs first; The PPS requests to strike every 6 visits from the language. Utilization of licensed physical therapists are a valuable resource in home health care, carrying out physical therapy treatments under the supervision of a licensed physical therapist. Many if not most state regulations call for on-site supervision of PTAs every 12 visits or 30 days. The 6 day supervision requirement greatly restricts the ability of PTs and PTAs to optimize the efficiency of carrying out these highly effective treatments. Physical Therapists are difficult to recruit, particularly in rural counties and by easing the supervision requirements it would insure that all patients are able to receive the full therapeutic benefit of their services.

**Response to Waiver Request:**

**Denied.** This requirement is in New York State Education law and we do not have the authority to waive statute.

**13 Millennium Collaborative Care Title: 10, Section 763.5a 2.b.viii**

**Background and Justification submitted with your request:**

The regulation states the initial patient visit shall be made within 24 hours of receipt and acceptance of a community referral or return home from institutional placement. The PPS requests this be changed to 48 hours. To have a consistent expectation that follows the Federal guideline of 48 hours. This will allow the agency the ability to prioritize care based on patient condition verses referral date within the first 48 hours.

**Response to Waiver Request:**

**Approved.** Federal regulation CFR 484.55 allows for an initial assessment visit by an R.N. or appropriate therapist (if a therapy-only case) within 48 hours of referral, inpatient discharge or on the physician ordered start of care date.

**14 Millennium Collaborative Care Title: 10 Section: 763.4 h 6 2.b.viii**

**Background and Justification submitted with your request:**

The regulation states that supervision of a home health aide or personal care aide is conducted by a registered professional nurse or licensed practical nurse or by a therapist if the aide carries out simple procedures as an extension of physical therapy, occupational therapy or speech/language pathology. The PPS requests the removal of "if the aide carries out simple procedures as an extension of physical therapy, occupational therapy or speech/language pathology." Licensed therapists are more than capable of supervising home health aides for Activity of Daily Living care as well as in the carrying out of simple Home Exercise Programs. In fact ADL training is a core teaching in both physical therapy and occupational therapy curriculums, and most states allow for this supervision to occur. By allowing therapists to also carry out home health aide supervisions, it will free up additional nursing resources to accomplish DSRIP projects.

**Response to Waiver Request:**

**No waiver needed.** Federal CFR 484.3(d) requires that a patient receiving skilled nursing care requires onsite supervision of the aide every 14 days, performed by a R.N. If the patient is not receiving skilled nursing care, but is receiving another skilled service (PT, OT or SLP), supervision may be provided by the appropriate therapist. Under 763.4, if the therapist is the "professional" supervising the aide (for therapy-only cases), the therapist would supervise all care provided by the aide, including assistance with Activity of Daily Living care.

**15 Millennium Collaborative Care Section 710.1 General provisions. Diagnostic and Treatment Centers / Urgent Care 2.b.iii**

**Background and Justification submitted with your request:**

Current regulatory requirements create an unfair competitive environment by requiring Article 28 facilities to go through the CON process when non-article 28 private practice groups can establish/construction DTC without DOH involvement.

**Response to Waiver Request:**

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

**16 Millennium Collaborative Care Section 406.1 Definition. 2.a.i**

**Background and Justification submitted with your request:**

For purposes of this section, a swing bed program operated by a rural hospital that has an approval from the Health Care Financing Administration (HCFA) to provide post hospital skilled nursing facility (SNF) care, shall mean beds used interchangeably as either general hospital or nursing home beds with reimbursement based on the specific type of care provided so that use of beds in this manner provides small hospitals with greater flexibility in meeting fluctuating demands for inpatient general hospital and nursing home care. To allow small (<100 bed) urban Article 28 facilities to operate Swing Beds. To avoid emergency requests to local offices for temporary permission to convert beds for volume surges.

**Response to Waiver Request:**

**Denied.** This is a federal requirement which we do not have the authority to waive.

**17 Millennium Collaborative Care 712-1.7 Psychiatric units. 3.a.ii**

**Background and Justification submitted with your request:**

The psychiatric unit, if included in a hospital as a separate nursing unit, shall have its program requirements approved by the Commissioner of the Department of Mental Hygiene. To relax the regulations required to establish new inpatient psychiatric specialty units (i.e: geriopsych). Many national behavioral health agencies with expertise in managing inpatient behavioral health units are unwilling to work with NYS Article 28 facilities due to the strict and cumbersome regulatory requirements that must be followed.

**Response to Waiver Request:**

**More Information needed. (OMH.)** Please e-mail additional clarification to Keith McCarthy of OMH at [Keith.McCarthy@omh.ny.gov](mailto:Keith.McCarthy@omh.ny.gov)

**18 Millennium Collaborative Care 709.3 Residential health care facility beds. 2.a.i**

**Background and Justification submitted with your request:**

Allow for a new category of RHCF pediatric beds at Highpointe: Pediatric Sub-Acute Long Term Care. These beds would allow Article 28 SNFs to care for pediatric patients with a combination of sub-acute and behavioral needs that no longer require an acute care hospital but are also not appropriate for psychiatric facilities. Currently, no such services are available in NYS and pediatric patients requiring such care are transferred out of state to facilities with limited capacity and long wait-lists.



**Response to Waiver Request:**

**Waiver not needed.** 10 NYCRR 709.3 is nursing home bed need methodology. It does not apply to pediatric nursing home beds. Pediatric units already receive specialty rates, which embrace the entire gamut of care rendered in the pediatric unit, including ventilator-dependent care and special medical, rehabilitative and educational needs for this population. The current system is addressing the needs of this population, including the most complex children, who will require a long nursing home stay, as well as children who require mainly rehabilitation prior to discharge to home.

**19 Millennium Collaborative Care 10 NYCRR 401.1: 10 NYCRR 401.2(b) 2.b.viii**

**Background and Justification submitted with your request:**

NFMMC seeks waiver authority to permit employed physicians and mid-levels to provide services outside of a certified service site and to be able to bill and receive reimbursement for the provision of primary care services at patient homes. In March 2015, the New York State Department of Health approved a waiver request from MCC to allow practitioners affiliated with Article 28 providers to provide services outside of the certified service site.

While the request was approved, the State indicated that reimbursement for the provision of such services would not be available absent approval of a State Plan Amendment to the State Medicaid Plan and revisions to associated state regulations. The Department of Health further indicated that it was pursuing necessary actions to permit the receipt of such reimbursement. MCC is called upon to refile a waiver request to enable Article 28 providers to conduct home visits. Such action will underscore the importance of permitting Article 28 providers to bill for such services.

NFMMC will be participating in the Hospital Home Care Collaboration project. To keep home care patients out of the ED and to avoid unnecessary admissions, visits to home care patients will be necessary to review medication regimens, conduct physical exams and retool the patient's at-home treatment plan. Without the ability to conduct and receive reimbursement for such home visits it will be difficult to fully advance the objectives of the Hospital Home Care Collaboration project.

**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.

In cases where waivers are approved, the agencies will send letters directed to the providers, who otherwise would be responsible for complying with the regulatory provisions at issue. Further, providers 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 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 e-mail 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.  
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