



# Department of Health

**ANDREW M. CUOMO**  
Governor

**HOWARD A. ZUCKER, M.D., J.D.**  
Commissioner

**SALLY DRESLIN, M.S., R.N.**  
Executive Deputy Commissioner

December 28, 2016

Millennium Collaborative Care PPS  
Richard Cleland, President, C.O.O. & Interim C.E.O.  
Erie County Medical Center  
462 Grider Street  
Buffalo, New York 14215

Dear Mr. Cleland:

On March 11, 2015, the Department of Health (Department), the Office of Mental Health (OMH), and the Office of Alcoholism and Substance Abuse Services (OASAS) were pleased to respond to the request for waivers from certain regulatory requirements submitted by Erie County Medical Center in its capacity as lead for the Millennium Collaborative Care PPS under the Delivery System Reform Incentive Payment (DSRIP) Program. In that letter, we notified you that your waiver request 48.02, related to CHHA expansion of service area, required additional review.

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

Accordingly, the pending regulatory waiver response below is for projects and activities as described in the Project Plan application and any implementation activities reasonably associated with those activities. The regulatory waiver 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, the regulatory waiver approved is only for the duration of the projects for which it was requested.

The approval of regulatory waivers is 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.

The specific pending request for regulatory waivers included in the Millennium Collaborative Care PPS Project Plan application is addressed below.

**48.02                      Millennium                      10 NYCRR 760.5                      2.b.viii**

**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:**

**Expansion of CHHA service area. Denied.** Article 36 of the Public Health Law mandates that service area expansions be based on a need methodology and further be subsequently approved by the Public Health and Health Planning Council (PHHPC). The DSRIP regulatory waiver authority does not permit the Department to waive statutory requirements. However, we recognize that more flexible regulatory models for approval of home and community-based care are essential for the State to achieve its health care system transformation goals. Development of such models are one of the topics being explored by the Department and PHHPC in a series ongoing public meetings. Your input in this process is encouraged and welcome.

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

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

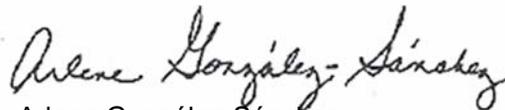
Sincerely,



Howard A. Zucker, M.D., J.D.  
Commissioner 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