



Department
of Health

Office of
Mental Health

Office of Alcoholism and
Substance Abuse Services

December 2, 2016

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

Dear Mr. Turner:

The New York State Department of Health (Department), 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 the Erie County Medical Center in its capacity as the lead for 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 for 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 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 request for a regulatory waiver is addressed below.

Background and justification provided in your request:

Millennium Collaborative Care is requesting regulation to be waived to allow for physician assistants and nurse practitioners working in the emergency department to oversee the administration or use of contrast medium. Hospitals are unable to afford employing physicians full time to cover the ED or remain in-house "24/7".

Response to waiver request: Denied. Public Health Law § 3501 (3) requires a licensed physician to directly supervise the administration of contrast media in the interest of public safety. Physician assistants or nurse practitioners can only be involved in the ordering of the contrast and evaluation of the patient's health prior to the test. DSRIP regulatory waiver authority does not permit the Department to waive statutory requirements. As such, this regulation cannot be waived.

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 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 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