



Department
of Health

Office of
Mental Health

Office of Alcoholism and
Substance Abuse Services

March 9, 2015

Catholic Medical Partners-Accountable Care IPA INC
SISTERS OF CHARITY HOSP
Dennis Horrigan, President & CEO
1083 Delaware Avenue
Buffalo, NY 14209

Dear Mr. Horrigan:

The Department of Health (DOH), 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 the Sisters of Charity Hospital in its capacity as lead for the Catholic Medical Partners-Accountable Care IPA INC 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, DOH, 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 Catholic Medical Partners-Accountable Care IPA INC PPS Project Plan application are addressed below.

46.01 Catholic Federal Anti-Kickback statute, Federal Start Law and PHL Section 238-a.

Background and justification provided in your request: Various federal and state provisions will have to be waived for all of the projects to allow revenue sharing across PPS participating organizations. Provisions in these laws will prevent our PPS from distributing funds within the PPS in the manner required by DSRIP.

Response to waiver request:

Denied. Federal and state statute may not be waived.

46.02 Catholic Title 10 New York Codes, Rules, and Regulations (NYCRR)

Background and justification provided in your request: Certificate of Need (CON) rules regarding establishment—specifically based on lead agency powers within the PPS—will require waiver of Part 405.1 & 600.9, regulatory provisions that define when establishment is required.

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).

46.03 Parts 405.3 & 600.9(c) rules regarding management contracts & revenue sharing will need to be waived.

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.

46.04 Definitive anti-trust protections are required (Certificate of Public Advantage will be helpful); broad state action immunity is necessary.

Response to waiver request:

No waiver needed. COPA regulations were effective on December 17, 2014. More information may be found at: http://www.health.ny.gov/health_care/medicaid/redesign/copa/

46.05 There is need for a centralized system-wide credentialing authority—involving facilities licensed by multiple state agencies & private practitioners—to include all practitioners who care for patients throughout our PPS (Parts 405.2 & 405.4).

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.

46.06 Since our PPS involves a community-wide practitioner base, corporate practice of medicine rules need to be addressed.

Response to waiver request:

Corporate Practice of Medicine. Denied. The PPS requested regulatory waivers in connection with the corporate practice of medicine, which is a statutory doctrine and therefore cannot be waived. This request is therefore denied. Please note, however, that the provision of health care services by an Accountable Care Organization (ACO) shall not be considered the practice of a profession under Education Law Title 8, and a PPS may submit an application for an ACO certificate of authority. See 10 NYCRR § 1003.14(f); http://www.health.ny.gov/health_care/medicaid/redesign/aco/docs/faqs.pdf.

46.07 Co-location restrictions need to be eliminated for services that integrate behavioral & physical health care & private physician practice. We envision this for 2ai & 3bi.

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. DOH, 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 DOH, 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.

46.08 To support the integration of primary care & behavioral health, hospitals need to be able to generate more than one threshold visit bill per day to support the costs of multiple providers of service. This is Part 86-4.9(b). Project 3ai.

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. DOH, 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 DOH, 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.

46.09 Practitioner home visits must be enabled/authorized for all Article 28 hospitals & diagnostic & treatment (D&T) centers. (Part 401.1).

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 DOH.

46.10 Substantial workforce flexibility must be enabled, especially as care provider roles change & staff transition to new roles. This is applicable to all projects.-Impediments to smooth and rapid transition of patients between care levels need to be waived [i.e., admission and discharge and transfer requirements in Parts 405.9 and 400.9, 400.11, 700.3, 415.38 (10 NYCRR), 505.20, and 540.5 (18 NYCRR)].

Response to waiver request:

Admission, Transfer and Discharge. No waiver needed. The PPS requested waivers of 10 NYCRR § 405.9(f)(7), 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.

More information needed including regulation citation, justification and impact on patient safety, should a waiver be needed with respect to workforce flexibility.

46.11 Flexibility, consistent with statute, with respect to use of observation services, needs to be enabled /supported (Part 405.19).

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.

46.12 Hospice need requirements & geographic limitations will need to be waived or eliminated—previous Public Health and Health Planning Council recommendation (Part 790).

Response to waiver request:

Determination pending.

46.13 Nursing home regulations, interpreted to protect the safety of other residents that compel nursing homes to transfer patients (especially behavioral patients) to hospitals, need to be modified to allow for appropriate therapeutic interventions within the nursing home (Part 415).

Response to waiver request:

More information needed. Please provide the specific regulation citation, justification, and impact on patient safety via email to DSRIP@health.ny.gov.

46.14 Home care ordering authority should be broadened to allow for medical directors, nurse practitioners, and physician assistants to sign orders for home care (Part 763).

Response to waiver request:

Determination pending.

46.15 Broader range of clinicians should be able to perform home health aide supervision, including utilizing methods other than on-site supervision (Part 763).

Response to waiver request:

Determination pending.

46.16 Certificate of public authority to enable PPS ACO's to take advantage of "safe harbors". Part 1003."

Response to waiver request:

No waiver needed. COPA regulations were effective on December 17, 2014. More information may be found at: http://www.health.ny.gov/health_care/medicaid/redesign/copa/

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