



Department
of Health

Office of
Mental Health

Office of Alcoholism and
Substance Abuse Services

March 12, 2015

Mr. Thomas Carman
Samaritan Medical Center
SAMARITAN MEDICAL CENTER
830 Washington Street
Watertown, New York 13601

Dear Mr. Carman:

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 Samaritan Medical Center in its capacity as lead for the Samaritan 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 Samaritan Medical Center PPS Project Plan application are addressed below.

45.01 Samaritan

Background and justification provided in your request:

(1) 2.a.i is implicated and it is a general concern regarding the PPS program. 2.a.i project requirements (9-10) are implicated because negotiating with private entities increases anti-trust risk. Article 29F and Proposed Regulations.

(2) There are ongoing anti-trust concerns for the PPS. NCI requests that the proposed regulations be adopted so that COPA can be applied for. The waiver would facilitate implementation of an integrated system by providing certainty as to the activities that the PPS may undertake without state action.

Response to waiver request:

COPA. Waiver not needed. COPA regulations have been adopted and are effective.

45.02 Samaritan

Background and justification provided in your request:

(1) The integrated delivery system of 2.a.i is generally implicated, but project requirement 10 is specifically implicated. 10 NYCRR 405.1(c).

(2) The PPS requests a waiver because the PPS will adopt certain policies on behalf of PPS Partners and will make certain decisions regarding the provision of healthcare to patients in the PPS. The PPS should be specifically exempted from this requirement because its activities with PPS Partners will not rise to the level of operating Partner facilities. The requirement for establishment would be overly burdensome and will delay the timely formation of the PPS.

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).

45.03 Samaritan

(1) 2.a.i is implicated and it is a general concern regarding the PPS program. 10 NYCRR 600.9(c)

Background and justification provided in your request:

(2) The PPS and its Partners and Affiliates will receive certain distributions of funds pursuant to the DSRIP program that could be construed as fee splitting. The PPS requests a waiver of the requirement that an entity that splits fees needs to have establishment approval.

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.

45.04 Samaritan

(1) 2.a.i. project requirements (4-7); 2.a.ii. project requirements (4-6); 2.a.iv. project requirements (4-6); 2.b.vi. project requirement (4-7); 2.d.i. project requirement 17; 3.a.i. project requirement 4; 3.b.i. project requirement (2, 8, and 11); 3.a.iv. project requirement 9; 3.g.i. project requirement 6; and 4.b.ii project requirement 4. Public Health Law § 18(6); Mental Hygiene Law § 33.13(c); Education Law 6530(23), Article 32 Privacy

Background and justification provided in your request:

2) Without a regulation PPS Partners and Affiliates will be subject to lawsuits from patients regarding uses and disclosures of healthcare information. The PPS requests that a regulation be promulgated that allows the PPS to obtain a single consent for treatment, payment, and healthcare operations uses and disclosures to settle liability under New York law. The regulation could specifically cite the Department consent form being developed.

Response to waiver request:

Consent. No waiver needed. The PPS requested regulatory waivers to the extent available to permit the use of a common consent form across providers. No regulatory waiver is needed for this purpose. The agencies are collaborating on the development of a consent model that would facilitate the ability of PPS providers to appropriately coordinate care and will share that model in the near future.

45.05 Samaritan All projects. 10 NYCRR 600.1; Parts 670; Parts 700

Background and justification provided in your request:

(2) The PPS requests that the Department, OMH, and OASAS create an integrated program for review of Public Need and Financial Feasibility for all PPS projects requiring CON or Prior Approval Review because requiring multiple agency review will make implementing the projects slower and more expensive.

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.

45.06 Samaritan All projects.

Background and justification provided in your request:

The PPS requests that the Public Health and Health Planning Council schedule a bi-weekly videoconference meeting to accommodate required approvals emanating from approved PPSs. The PPS requests that the Behavioral Health Services Advisory Council schedule a monthly videoconference meeting to accommodate required approvals emanating from approved PPSs.

Response to waiver request:

Bi-weekly videoconferences to expedite approvals. Not applicable as a regulatory waiver was not requested. We will expedite all approvals associated with DSRIP projects. The suggestion will be taken into consideration.

45.07 Samaritan

(1) 2.a.iv. Project requirement 1. All projects involving bed and service relocations between Partners. 10 NYCRR 708.3(e); 10 NYCRR 708.4; 10 NYCRR 710.1(c)(4)(iv); 10 NYCRR 710.1(c)(5)(iv)

Background and justification provided in your request:

(2) The PPS requests an accelerated review requirement for bed and service relocations between PPS Partners. The bed and service relocations should only require letter notification to the Department and the review should be deemed to occur after 15 days. There is authority for this in 10 NYCRR 710.1(c)(4)(iv) which allows for certain changes to be made without an application and for limited review under 10 NYCRR 710.1(c)(5)(iv). The 180 day review period in 10 NYCRR 708.3(e) could be shortened to 15 days. This requires eliminating the specific 10 NYCRR 708.4(a) review criteria and substituting whether the relocations fit into the PPS's overall plan.

Response to waiver request:

Bed Capacity. Approved. The PPS requested waivers for regulations related to changes in bed capacity. 10 NYCRR §§ 710 and 401(e), pertaining to the CON process for changes in bed capacity, are approved provided that submission of information through NYSE-CON is necessary for decreases in bed capacity and administrative review necessary for increases in bed capacity. The Department will expedite all DSRIP projects.

45.08 Samaritan

(1) If 2.a.i. is successful it will reduce the overall number of patients being admitted as inpatients. This may cause certain facilities or components of facilities to close. 10 NYCRR 401.3(g)

Background and justification provided in your request:

(2) The PPS requests that the 90-day timeline for the Department to consider facility or component closure be reduced to 30 days to facilitate timely closures where it is necessary due to the PPS achieving its goals.

Response to waiver request:

Facility Closure. Denied. The PPS requested regulatory waivers in connection with the closure of a facility. While the Department will expedite approvals 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 requests therefore are denied.

45.09 Samaritan

(1) 2.a.i. and all projects dealing with creating an integrated delivery system. Education Law §§ 6512, 6513, 6509(9), 6509-a.

Background and justification provided in your request:

(2) The PPS requests that a regulation be promulgated clarifying that the activities of a PPS would not constitute the practice of medicine. In particular, the PPS requests clarification that the creation of a single system of credentialing within the PPS does not constitute the corporate practice of medicine.

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

45.10 Samaritan

(1) 2.a.i. project requirements (4-7); 2.a.ii. project requirements (4-6); 2.a.iv. project requirements (4-6); 2.b.vi. project requirement (4-7); 2c.i. project requirements (6-7) 2.d.i. project requirement 19; 3.a.i. project requirement 4; 3.b.i. project requirement (2-5); and 4.b.ii project requirement 4. 10 NYCRR § 401.3(a)

Background and justification provided in your request:

(2) The PPS requests a waiver to forgo prior review, regardless of cost, for acquisition, installation, and modification, and any capital outlay associated with purchase of EHR for PPS Partners.

Response to waiver request:

HIT Standards. Approved. The PPS requested waivers of pertaining to CON review of Health Information Technology (HIT) changes in existing medical facilities. The waiver request is approved to waive 10 NYCRR § 710.1(b) regarding the financial review, however the Department must review each project on a case-by-case basis to ensure IT standards are met.

The PPS should contact the Department's Office of Health Information Technology (OHIT) for approval. To do so, please contact: SHIN-NY@health.ny.gov.

45.11 Samaritan

(1) 2.a.i. project requirements (4-7); 2.a.ii. project requirements (4-6); 2.a.iv. project requirements (4-6); 2.b.vi. project requirement (4-7); 2c.i. project requirements (6-7) 2.d.i. project requirement 19; 3.a.i. project requirement 4; 3.b.i. project requirement (2-5); and 4.b.ii project requirement 4. 10 NYCRR §§ 710.1(2), 710.1(3)(i)(q), 710.1(5)(iv)(g).

Background and justification provided in your request:

(2) All of these project require use of HIT technologies and interoperability, this will require investment in new EHR technologies, capital and vendor services. The waiver is necessary so that the PPS and all partners do not need further review or approval from the Department regarding HIT acquisition, installation, modification or outlay of capital to implement necessary technology advances to participate in DSRIP project.

Response to waiver request:

HIT Standards. Approved. The PPS requested waivers of pertaining to CON review of Health Information Technology (HIT) changes in existing medical facilities. The waiver request is approved to waive 10 NYCRR § 710.1(b) regarding the financial review, however the Department must review each project on a case-by-case basis to ensure IT standards are met. The PPS should contact the Department's Office of Health Information Technology (OHIT) for approval. To do so, please contact: SHIN-NY@health.ny.gov.

45.12 Samaritan

(1) All Projects dealing with integration of services will face scope of practice issues. (2) The PPS requests that the Department exercise its authority to formally approve each PPS and its treating partners in order to become exempted from these scope of practice provisions for the professions of:

- Social Work (Education Law, Article 154),
- Psychology (Education Law, Article, 153),
- Mental Health Practitioners (Education Law, Article 163).

Background and justification provided in your request:

The authority for this is Section 9 of Chapter 420 of the Laws of 2002, as amended by chapter 132 of the laws of 2010, relating to the profession of social work; Subdivision a. of Section 17-a of chapter 676 of the laws of 2002, as amended by chapters 130 and 132 of the laws of 2010, and as further amended by chapter 57 of the laws of 2013, in relation to the profession of psychology and the four professions described as mental health practitioners. The PPS also requests the extension of this scope of practice exemption beyond its July 1, 2016 sunset date.

Response to waiver request:

Scope of Practice. Denied. We do not have the authority to waive State statute.

45.13 Samaritan

(1) All projects that plan to utilize the integrated outpatient services regulations. 10 NYCRR 600.2

Background and justification provided in your request:

(2) The PPS requests in numerous locations that the Department adopt the proposed integrated outpatient services regulations so that the PPS can adopt those regulations. In the interim, the PPS requests that for all projects where it has indicated a desire to utilize these regulations the Department grant a waiver or approval under 10 NYCRR 600.2 to allow the PPS to begin the process of undertaking the selected projects in the interim in situations where primary care services will be provided at a facility licensed by OASAS or OMH.

Response to waiver request:

Integrated outpatient services. Waiver not needed. Regulations have been adopted and are in effect.

45.14 Samaritan

(1) All projects that plan to utilize observation beds. 10 NYCRR 405.19 (g) (2,5 (b)); 10 NYCRR 710.1(c)(2) or (3)

Background and justification provided in your request:

(2) The PPS requests a waiver to increase number of observation beds and a waiver physical space and location and Construction requirements for those beds regardless of cost. The PPS will comply with the applicable provisions of Parts 711 and 712-2 and section 712-2.4 of this Title for construction projects approved or completed after January 1, 2011.

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.

45.15 Samaritan

(1) All projects that are impacted are by the use of telemedicine to make decisions about transferring residents from SNFs when physicians, nurses and other clinical staff with the necessary training to make the transfer decision are not available. 10 NYCRR 400.9 (c)(1) and (d).

Background and justification provided in your request:

(2) 10 NYCRR 400.9(c)(1) requires the personal, alternate or staff physician requests or agrees to the admission, transfer or discharge from a skilled nursing facility. The reasons for the waiver request is to allow transfer decisions to be evaluated in a timely way by health care professionals with the necessary expertise to facilitate transfers as needed, and avoid preventable transfers undertaken because of the unavailability of health care professionals at the SNF to evaluate the resident and make a transfer decision by utilizing tele-health and telemedicine services.

Response to waiver request:

Tele-health. Approve. This request is approved but requires policies and procedures that state the circumstances under which telemedicine can be used for this specific purpose. The policies and procedures should state that only the resident's physician of record, or the

physician who is covering for the resident's physician of record, can make the decision to admit, transfer or discharge.

45.16 Samaritan

(1) 2.a.i. project requirement 8; 2.d.i. project requirements 6 and 10; 3.a.ii project requirement 3. 10 NYCRR § 98-1.5(b)(6)(vii)

Background and justification provided in your request:

(2) The PPS will contract with Medicaid Managed Care Organizations as an integrated system and establish value based payment arrangements. This could require licensure as an IPA under 10 NYCRR 98-1.5(b)(6)(7). The PPS requests a waiver of the restriction on MCOs contracting with unlicensed entities for IPA services and recognize that the PPS may perform some IPA services. The PPS requests that it be exempt from the definition of an IPA under 10 NYCRR 98-1.2 (w).

Response to waiver request:

Denied - In NYS, MCOs can only contract with providers and IPAs to arrange for the provision of services. At this time, MCOs contracting requirements and limitations cannot be waived. Legislation has been proposed to allow MCOs to contract directly with PPS entities without them becoming an IPA, however, many of the requirements of IPAs would be applicable and enforced.

45.17 Samaritan (1) 2.a.i. project requirement 9. Public Health Law § 4901(9)(c)

Background and justification provided in your request:

(2) The PPS requests that regulations be promulgated indicating that the PPS is not a utilization review agent due to the Public Health Law § 4901(9)(c) exception. The Public Health Law provides that agents acting on behalf of the state and local government for services provided pursuant to title XIX of the federal social security act are not utilization review agents. The PPS will be analyzing utilization and medical necessity of various treatments, especially inpatient hospitalization, and could be deemed a utilization review agent.

Response to waiver request:

Denied. If the PPS is making medical necessity determinations such as authorizing and denying services, they are a UR agent and we cannot waive a statutory provision.

45.18 Samaritan

(1) 2.a.i. project requirement 11; 2.d.i. project requirements 11 and 13; 4.a.iii project requirement 4 the PPS intends to share PPS data elements gathered from across the PPS with trainers in MEB health promotion. Public Health Law § 18(6);Mental Hygiene Law § 33.13(c);Education Law § 6530(23);Article 32 Privacy

Background and justification provided in your request:

(2) It would be a treatment purposes disclosure for the PPS to disclose information to healthcare providers within the PPS. However, it is not a treatment purposes disclosure to disclose information to engage patients in the integrated delivery system through outreach. As such, the consent form the Department is currently drafting needs to be a HIPAA compliant authorization for these activities. The consent form should only need to be obtained once to

allow the PPS to conduct all activities required under the project plans. However, an authorization needs to be specific as to the entity the information is to be released to. Therefore, the Department will need to consult with CMS in drafting the authorization to determine if reference in the consent to an online list of PPS Partners and Affiliates will be sufficient for an authorization.

Response to waiver request:

Consent. No waiver needed. The PPS requested regulatory waivers to the extent available to permit the use of a common consent form across providers. No regulatory waiver is needed for this purpose. The agencies are collaborating on the development of a consent model that would facilitate the ability of PPS providers to appropriately coordinate care and will share that model in the near future.

45.19 Samaritan

(1) 2.a.ii project requirement 8 dealing with behavioral health screening protocols. 10 NYCRR §§ 405.2(e)(3), 405.4(b)(4), 94(b)(2-3)

Background and justification provided in your request:

(2) The PPS requests that providers be allowed to be credentialed to conduct the BH screenings at the PPS level. Effective PPS preventative care screening will require providers with appropriate credentials to be available in facilities that do not currently credential providers for BH screenings. This will enable the creation of a single community wide practitioner base and waiver of these various state agency requirements. Administrative delays relating to multiple credentialing processes of the State and MCOs can impede a PPS's ability to provide access to care.

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 Response. OASAS requests additional information from the PPS including specifics of who will be credentialed and the type of behavioral health screens will be provided.

45.20 Samaritan

(1) 2.a.iv project requirement 1. 10 NYCRR § 710.1(c)(1-5,7) - add or change method of service

Background and justification provided in your request:

(2) The PPS requests a waiver of the requirements of department approval of changes to the extent and kind of services to be provided at PPS Partner Article 28 facilities. The PPS requests a waiver of the factors for determining public need and the specific review process. The PPS requests a waiver of the requirement determination of public need and prior review and approval. The PPS requests that such approval be deemed granted upon review and approval of this application and any supplemental filings regarding specific projects. This is necessary in order to convert outdated and unneeded hospital infrastructure and programs into other types of hospital based programs within a medical village. The process of applying for

department approval would be time consuming especially given the number of requests within the next several years.

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, 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.

45.21 Samaritan

(1) 2.a.iv project requirement 1. 10 NYCRR §§ 401.3(e), 670.1 (a-b), 710.1(c)(1)(v).

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Background and justification provided in your request:

(2) The PPS requests waiver of need for new CON and need methodology for determination of public need and prior review and approval of decreases in bed capacity. The PPS proposes that approval of the DSRIP Project application be deemed approval of any bed reduction contained therein. However, the PPS requests that if prior review is required that the Department only require letter notification going forward.

Response to waiver request:

Bed Capacity. Approved. The PPS requested waivers of 10 NYCRR §§ 710 and 401(e), pertaining to the CON process for changes in bed capacity. These requests are approved, provided that submission of information through NYSE-CON is necessary for decreases in bed capacity and administrative review necessary for increases in bed capacity. The Department will expedite all DSRIP projects.

45.22 Samaritan

(1) 2.a.iv project requirement 1. 10 NYCRR 401.3(g) - reduce or eliminate a service

Background and justification provided in your request:

(2) The PPS requests that the Department reduce the notice period of 401.3(g) from 90 to 30 days. The reduced period will address the need to rapidly change and reconfigure services. This is necessary to allow changes to healthcare delivery in a timely fashion due to the high volume of such requests throughout the state.

Response to waiver request:

Facility Closure. Denied. The PPS requested regulatory waivers in connection with the closure of a facility. While the Department will expedite approvals 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 requests therefore are denied.

45.23 Samaritan

Background and justification provided in your request:

The PPS requests that the Department finalize the proposed telehealth and telemedicine regulations.

Response to waiver request:

Telehealth regulations. More information needed. The Department seeks clarification regarding the specific regulations being referenced. Please provide such information via e-mail to DSRIP@health.ny.gov.

45.24 Samaritan

(1) 2.a.iv project requirement 1 for each Medical Village utilizing PC and BH integration; 3.a.i. – North Country Family Health Center integration with Community Clinic of Jefferson County, North Country Family Health Center integration with Transitional Living Services, Community Health Center of the North Country Ogdensburg expansion, Community Services and Claxton Hepburn Article 28 Primary care co-locations. 10 NYCRR 401.3 (a)(1-3) and 710.1 (b) (c)(1-5, 7) - Change physical plant

Background and justification provided in your request:

(2) The PPS requests that the Department grant a waiver of the requirement for determinations of public need and prior review and approval for construction projects contained in the DSRIP Project application. To the extent review is deemed necessary, the PPS requests that the Department only require limited review or architectural review only.

Response to waiver request:

Public Need and Financial Feasibility. Approved. The PPS requested waivers of 10 with respect to the public need and financial feasibility components of the CON process. Waivers are approved for 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.

Construction Standards. Denied. The PPS requested waivers of §§ 401.3 which sets forth construction standards. Due to patient safety concerns, these regulations cannot be waived. However, the Department will expedite the review of projects associated with DSRIP Project Plans to the extent possible.

45.25 Samaritan

1) 2.a.iv project requirement 1 for each Medical Village utilizing PC and BH integration; 3.a.i. – North Country Family Health Center integration with Community Clinic of Jefferson County, North Country Family Health Center integration with Transitional Living Services, Community Health Center of the North Country Ogdensburg

expansion, Community Services and Claxton Hepburn Article 28 Primary care co-locations 10 NYCRR §§ 710.7(b-c) 710.7 (d) - Expedited Construction

Background and justification provided in your request:

(2) The PPS requests that a waiver of the requirement that the Department advise the PPS in writing that it can commence construction under 10 NYCRR 710.7 (d) and instead deem the submission under section 710.7(b-c) of the regulations complete after 15 days. This is necessary to ensure the ability to rapidly commence construction and renovation projects within the 3 year implementation period for DSRIP.

Response to waiver request:

Approval to start construction. Approvable on a case by case basis. 10NYCRR 710.7(a) states that the applicant may seek approval to start construction of the project, or one or more phases thereof, upon the filing with the department completed contract documents consistent with all previous approvals. The Department will review such requests on a case by case basis and will expedite the review of all DSRIP projects.

45.26 Samaritan

(1) 2.a.iv project requirement 1 for each Medical Village utilizing PC and BH integration; 3.a.i. – North Country Family Health Center integration with Community Clinic of Jefferson County, North Country Family Health Center integration with Transitional Living Services, Community Health Center of the North Country Ogdensburg expansion, Community Services and Claxton Hepburn Article 28 Primary care co-locations 10 NYCRR 710.9

Background and justification provided in your request:

(2) The PPS requests that the Department expedite the pre-opening inspection and survey to within 15 days and allow the facility to remain open while non-patient areas are under review. This is necessary to ensure the ability to rapidly begin operation once renovation and building projects are complete.

Response to waiver request:

Pre-Opening Surveys. Denied. The PPS requested waivers of 10 NYCRR § 701.9, pertaining to CON pre-opening surveys. These requests are denied, as pre-opening surveys pertain to patient safety. However, the Department will expedite pre-opening surveys connected with DSRIP projects to the extent possible.

45.27 Samaritan

(1) 2.a.iv project requirement 1 for each Medical Village utilizing PC and BH integration; 3.a.i. – North Country Family Health Center integration with Community Clinic of Jefferson County, North Country Family Health Center integration with Transitional Living Services, Community Services and Claxton Hepburn Article 28 Primary care co-locations 10 NYCRR 703.6

Background and justification provided in your request:

(2) The PPS requests that the Department treat extension clinics and diagnostic and treatment centers as part time clinics under 10 NYCRR 710.6 for purposes of review the construction and operating standards for each project. The waiver is necessary to aid the PPS during the transition phase.

Response to waiver request:

Approvable on a case-by-case basis.

45.28 Samaritan

Background and justification provided in your request:

The PPS requests that the Department petition CMS to allow the Department to waive CMS colocation requirements when it is deemed in the best interests of promoting the objectives of DSRIP.

Response to waiver request:

Petition CMS to change their requirements. Not applicable as regulatory waiver not requested. This request will be taken into advisement.

45.29 Samaritan

(1) 3.a.i. – Samaritan Medical Center will integrate behavioral health into seven hub PCP practices, Carthage Area hospital at 1 hub site, River hospital at one site, Claxton Hepburn at 1 site and Massena Memorial at 1 site; 3.a.i project requirement 2.14 NYCRR § 599-1 -

Background and justification provided in your request:

(2) The PPS intends to utilize the proposed integrated outpatient services center regulations once those regulations are promulgated. The PPS requests that those regulations be finalized as soon as possible. The PPS requests that approval of this application be deemed approval of the integrated services center application under 14 NYCRR § 599-1.15(f). In the alternative, the PPS requests that any multiple agency reviews be consolidated into a single review process to expedite the authorization for 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.

45.31 Samaritan

(1) 3.a.i North Country Family Health Center will provide primary care services to patients at Children’s Clinic of Jefferson County and Transitional Living Services. 14 NYCRR 587.4 (7)

Background and justification provided in your request:

(2) 14 NYCRR 587.4 (7) defines a provider of service as an entity that is responsible for operation of a program. The remainder of that part imposes certain requirements on providers of services for the operation of outpatient programs. The PPS requests a waiver of the definition of a provider of service to exclude primary care practices, like NCFHC, from complying with the requirements of that subpart applicable to providers of services when co-located with a licensed provider of services.

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.

45.32 Samaritan

(1) The Projects requested for: 2biv to permit providers to implement PPS-approved protocols for care transitions and care pathways, protocols to manage patients in appropriate settings and implement project goals to reduce ED and inpatient hospital usage. 10 NYCRR 405.9 (b)(2)

Background and justification provided in your request:

(2) The regulation requested for waiver is 10 NYCRR 405.9 (b)(2).

Response to waiver request:

Admission, Transfer and Discharge. No waiver needed. The PPS requested waivers to regulations 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.

45.33 Samaritan

10 NYCRR 405.9 (f)(7)

Background and justification provided in your request:

The regulation requested for waiver is 10 NYCRR 405.9 (f) (7). The Projects requested for: 2biv to permit providers to implement PPS-approved protocols for care transitions and care pathways, protocols to manage patients in appropriate settings and implement project goals to discharge patients to the appropriate post-acute setting. There are not alternatives to this request since the source of patient is a factor in identifying patients who may be included in

certain programs. To reduce the patient safety concern, clinical governance will include competent professionals to ensure that protocols are safe and appropriate and staff will be trained to focus on patient safety and Quality. Outcomes will be closely monitored to ensure that implementation does not have an adverse impact on patient care.

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.

45.34 Samaritan 10 NYCRR 405.9 (f)(3)(ii)

Background and justification provided in your request:

The regulation requested for waiver is 10 NYCRR 405.9 (f) (7). The Projects requested for: 2biv to permit providers to implement PPS-approved protocols for care transitions and care pathways, protocols to manage patients in appropriate settings and implement project goals to discharge patients to the appropriate post-acute setting. There are not alternatives to this request since the source of patient is a factor in identifying patients who may be included in certain programs. To reduce the patient safety concern, clinical governance will include competent professionals to ensure that protocols are safe and appropriate and staff will be trained to focus on patient safety and Quality. Outcomes will be closely monitored to ensure that implementation does not have an adverse impact on patient care.

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.

45.35 Samaritan

(1) 2.a.i Health Home Care managers are an integral component of the IDS and as a key component of their role to insure that beneficiaries have access to the community-based services to remain out of the ER and inpatient admissions. 18 NYCRR Section 505.10(c)(2)

Background and justification provided in your request:

(2) The PPS requests a waiver of the limitation that restricts transport to pharmacy and preventive services such as the Diabetes Prevention Program and tobacco cessation sites or to access nutrition. This is necessary in order to ensure the high-risk Medicaid health home patients have access to preventive services.

Response to waiver request:

Transportation to non-medical destinations. Denied. This waiver requests payment for transportation services to non-medical destinations such as diabetes prevention programs, smoking cessation sites and nutrition services. Such programs are not currently covered by the Medicaid transportation benefit.

45.36 Samaritan

(1) 2.a.i Health Home Care managers are an integral component of the IDS and as a key component of their role to insure that beneficiaries have access to the community-based services to remain out of the ER and inpatient admissions. 18 NYCRR Section 505.10(c)(2)

Background and justification provided in your request:

(2) The PPS requests the Department to approve and include Health Home care managers as other type of medical practitioner approved by the Department, as allowed under the regulation

Response to waiver request:

Waiver not needed. The Department currently allows Health Home care managers to request transportation to Medicaid covered services.

45.37 Samaritan

(1) 2.a.i Timely and available Home Care is a critical component of the Integrate Delivery System to insure patients are well managed in the outpatient setting. At this time there is only one CHHA serving Lewis County. Providers report difficulty finding home care services for their discharged patients following joint replacement and other inpatient releases. 10NYCRR Part 760

Background and justification provided in your request:

(2) The PPS requests a waiver to allow those CHHAs already licensed to provide services in the other counties of the Tug Hill Seaway region to extend the geographic service are to include Lewis County.

Response to waiver request:

CHHA expansion of services. Determination pending.

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.

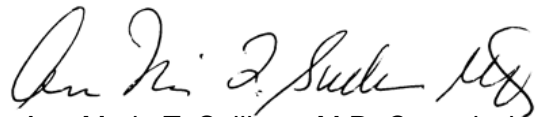
Please note that the Department of Health will publish on its website a list of regulatory waivers that have been approved to assist PPSs in determining whether additional waivers may be appropriate for the activities within a PPS. Additional requests for waivers, as well as any questions regarding the 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