



**Department
of Health**

Medicaid
Redesign Team

DSRIP REGULATORY WAIVER REQUESTS AND DETERMINATIONS

Office of Primary Care and Health Systems Management

Requests for Regulatory Waivers

- 536 requests were received for regulatory waivers from 24 PPSs
- Coordinated review process by DOH, OMH, OASAS and OPWDD
- Response letters have been sent to all 24 PPSs

Review Process Considerations

- Consistent with a federal requirement?
- Consistent with state statute?
- Consistent with patient safety considerations?
- Consistent with important public policy principle(s)?

Most Common Requests by Category

- **Integrated Services**
- **Public Need and Financial Feasibility**
- **Admission, Transfer, Discharge**
- **Offsite Services**
- **Revenue Sharing**
- **Administrative Services**
- **Bed Capacity**
- **Transfer and Affiliation agreements**
- **Tele-health**
- **HIT Standards**

Responses by Category

- Waiver determinations- Total 536
 - Approved-243
 - Denied-95
 - No Waiver Needed-89
 - Determination Pending-23
 - Approvable on a Case-by-Case Basis-31
 - More Information Needed-47
 - Not applicable-Waiver Not Requested-8

Ownership and Management

Revenue Sharing

Regulation: 10 NYCRR 600.9(c)

- **Nature of Requirement:** The regulation at 10 NYCRR 600.9(c) provides that “an individual, partnership or corporation which has not received establishment approval may not participate in the total gross income or net revenue of a medical facility.”
- **Determination:** Waiver requests were **approved** to the extent that the regulation otherwise would prohibit providers from receiving DSRIP incentive payments distributed by the PPS Lead.

Administrative Functions of PPS

Regulation: 10 NYCRR 405.1(c)

- **Nature of Requirement:** The regulation at 10 NYCRR § 405.1(c) provides that “any person . . . or other entity with the authority to operate a hospital must be approved for establishment by the [Public Health and Health Planning Council] unless otherwise permitted to operate by the Public Health Law . . .” It defines an “operator” of a hospital as an entity with “decision-making authority” over any of the active parent powers listed under 405.1(c).
- **Determination: No waiver needed** unless the PPS, the PPS lead, or any other provider in the PPS, is performing functions described in 10 NYCRR § 405.1(c) and thus acts as the active parent of another entity, which requires establishment as set forth in § 405.1(c). Establishment cannot be waived as it is required by PHL 2801-a(1) and all establishment requests must go through PHHPC.

Management Contracts Regulations: 10 NYCRR § 600.9(d) and 10 NYCRR 405.3(f)

- **Nature of Requirements:** The regulation at 10 NYCRR § 600.9(d) provides that the governing authority of a hospital may not contract for management services with a party which has not received establishment approval, except as permitted under 10 NYCRR § 405.3. 10 NYCRR § 405.3(f) requires DOH approval of management contracts, under which the governing body of a general hospital contracts with an entity to assume the day-to-day operations of the entire facility or a unit of the facility.
- **Determination:** If a PPS, a PPS lead, or any provider within a PPS, is managing the daily operations of another licensed entity, the entity that is assuming management responsibility must be established as operator of that site through PHHPC. If two or more providers enter into a Management Services Agreement(MSA), the Department **cannot waive** the requirement for DOH approval of the MSA due to potential establishment implications.

Corporate Practice of Medicine

- PPSs have requested waivers of the corporate practice of medicine doctrine. The corporate practice of medicine is a statutory doctrine and **cannot be waived**.
- However, 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.

Integrated Services

- PPS's requested waivers to allow:
 - The provision of primary care and/or substance abuse services in a facility licensed by OMH; OR
 - The provision of mental health and/or substance abuse services in a facility licensed by DOH; OR
 - The provision of primary care and/or mental health services in a facility licensed by OASAS
- Up to 49% of visits WITHOUT requiring an additional license.

Integrated Services

Integrated services. Waivers were **approved** with respect to 14 NYCRR 599.4(r) and (ab), contingent upon following the DSRIP Project 3.a.i Integrated Services Model (Licensure Threshold Model). DOH, OMH and OASAS have determined that no additional waivers are needed if providers are integrating services under such model. 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.

Integrated Services - Reimbursement Regulation: 10 NYCRR 86-4.9(b)

Nature of Requirement: The regulation at 10 NYCRR 86-4.9(b) provides that a threshold visit, including all part-time clinic visits, shall occur each time a patient crosses the threshold of a facility to receive medical care without regard to the number of services provided during that visit. Only one threshold visit per patient per day shall be allowable for reimbursement purposes, except for transfusion services to hemophiliacs, in which case each transfusion visit shall constitute an allowable threshold visit.

Determination: If the DSRIP Integrated Services Model is implemented, all services provided to the patient on a specific day can be billed. Billing Guidance is provided in the DSRIP Integrated Services Model.

Certificate of Need

CON

Regulations: 10 NYCRR 670.1, 709 and 710.2

Nature of Requirements: The regulations at 10 NYCRR 670.1, 709 and 710.2 set forth the methodologies used to determine public need and financial feasibility components of the CON process.

Determination:

- Financial feasibility is waived
- Waivers cannot be granted for establishment applications because of statutory limitations
- Projects involving construction, regardless of other waivers, must file a construction application through NYSE-CON due to the potential for patient safety implications

Certificate Of Need

- CHHA Service Area Expansion
- Hospice Service Area Expansion
- High Technology Specialty Services (e.g., cardiac services, therapeutic radiology, organ transplantation, etc.)

Determination Pending

CON - Changes in Bed Capacity

Regulation: 10 NYCRR 401.3(e) and 710.1 (c)(2)

Nature of Requirement: The regulations at 10 NYCRR 401.3(e) and 710.1(c)(2) pertain to the CON process for changes in bed capacity.

Determination: For bed decreases a limited review application is still required. Hospital and nursing home bed increases will be subject to public need review, but processed through administrative (rather than full) CON review. DOH will expedite all applications related to DSRIP projects.

CON - Transfers of Beds Between Hospitals Regulation: 10 NYCRR 401.1

Nature of Requirement: The regulation at 10 NYCRR 401.1 pertains to transfers of beds within an Article 28 network.

Determination: Waivers are not needed. Transfers and relocations of beds and services between general hospitals within an established Article 28 network as defined in 10 NYCRR 401.1 are subject only to limited review, submitted through NYSE-CON.

CON - HIT Changes Regulation: 10 NYCRR 710.1(b)

Nature of Requirement: The regulation 10 NYCRR § 710.1(b) pertains to CON review of Health Information Technology (HIT) changes in existing medical facilities.

Determination: Waiver requests were **approved** to waive the financial review, however DOH must review each project on a case-by-case basis to ensure IT standards are met. The PPS should contact DOH's Office of Health Information Technology (OHIT) for approval. To do so, please contact: SHIN-NY@health.ny.gov.

DOH Approval to Commence Construction

Regulation: 10 NYCRR 710.7(d)

Nature of Requirement: 10 NYCRR § 710.7(d) states that when submission [requirements] under subdivision (a) or (b) of this section are deemed complete by DOH, the applicant must be advised in writing to commence construction pursuant to Part 710. 10 NYCRR 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 DOH completed contract documents consistent with all previous approvals. 10 NYCRR 710.7(b) states that if documents are not completed, the applicant may request approval to start construction upon submission of a certification as described in such subdivision.

Determination: Waiver requests are **approvable on a case-by-case basis**. The Department will expedite review of DSRIP projects.

Construction Standards

Regulations: 10 NYCRR 401.3, Part 711, Part 712, Part 713, Part 714 and Part 715

Nature of Requirements: The regulations at 10 NYCRR 401.3 and Parts 711 through 715 set forth construction standards.

Determination: Waiver requests were **denied** due to potential patient safety implications. DOH will expedite the review of DSRIP projects.

Pre-Opening Surveys

Regulation: 10 NYCRR 710.9

Nature of Requirement: The regulation at 10 NYCRR 710.9 regulates onsite inspection or pre-opening survey of projects requiring DOH approval before an operating certificate may be issued or occupation of the facility.

Determination: Waiver requests were **denied** due to potential patient safety implications. DOH will expedite the review of DSRIP projects.

Operating Standards

Admission, Transfer and Discharge within PPS

Regulation: 10 NYCRR § 405.9(f)(7)

Nature of Requirement: The regulation at 405.9(f)(7) requires hospitals to "ensure that no person presented for medical care shall be removed, transferred or discharged from a hospital based upon source of payment."

Determination: No 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.

Credentialing

Regulations: 10 NYCRR 405.2(e)(3) and 405.4(c)(5)

Nature of Requirements: The regulation at 10 NYCRR 405.2(e)(3) provides that the governing staff shall ensure the implementation of written criteria for selection, appointment and reappointment of medical staff members and for the delineation of their medical privileges. Such criteria shall include standards for individual character, competence, training, experience, judgment, and physical and mental capabilities. 10 NYCRR 405.4 requires hospitals have an organized medical staff that operates under bylaws approved by the governing body. More specifically, 10 NYCRR 405.4(c)(5) mandates that the medical staff adopt and enforce by laws to carry out its responsibilities. The bylaws must at minimum set forth criteria and procedures for recommending the privileges to be granted to individual practitioners, contain a procedure for applying the criteria and procedures to individuals requesting privileges, and be consistent with the requirements contained in section 405.6 of this Part.

Determination: Waiver requests were **approved** 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. There must be a process in place for each provider in the PPS. Each individual practitioner must be privileged by each facility.



Transfer Agreements

Regulation: 10 NYCRR 400.9

Nature of Requirement: The regulation at 10 NYCRR 400.9 governs transfer and affiliation agreements.

Determination: No waiver is needed provided that the PPS has already established such agreements among the partners within the PPS.

Off-Site Services

Regulation: 10 NYCRR 401.2(b)

Nature of Requirement: The regulation at 10 NYCRR 401.2(b) provides that an operator may use an operating certificate only for the designated site of operation; except where the Commissioner authorizes temporary operation at an alternate site due to an emergency.

Determination: Waiver requests will be **approved** contingent upon notification by the PPS of the specific providers, practitioners and services. However, reimbursement for the provision of such services would require approval of a State Plan Amendment (SPA) to the State Medicaid Plan and associated state regulations, both of which are being pursued by DOH. In addition, DOH will explore, through Value-based Payment options, incorporating more flexibility for home visits, telemedicine and team visits.

Observation Beds

Regulation: 10 NYCRR § 405.19(g)(2)(i), (ii) and (v)

- **Nature of Requirement:** The regulation at 10 NYCRR 405.19(g)(2)(i) provides that “[t]he total number of dedicated observation unit beds in a hospital shall be limited to five percent of the hospital's certified bed capacity, and shall not exceed forty, provided that in a hospital with less than 100 certified beds, an observation unit may have up to five beds. 10 NYCRR 405.19(g)(2)(ii) provides that “[t]he observation unit shall be located within a distinct physical space, except in a hospital designated as a critical access hospital...” and 10 NYCRR 405.19(g)(2)(v) provides that “[t]he observation unit shall be marked with a clear and conspicuous sign that states: "This is an observation unit for visits of up to 24 hours. Patients in this unit are not admitted for inpatient services."
- **Determination:** Waiver requests were **approved** to allow observation unit stays up to 48 hours. Regulatory waivers were not needed for a provider to increase its number of observation beds. Construction standards, if applicable, cannot be waived.

Construction Requirements-Observation Units Regulation: 10 NYCRR § 405.19(g)(2)(iii)

Nature of Requirement: The regulation at 405.19(g)(2)(iii) provides that “[t]he observation unit shall 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.”

Determination: Waiver requests were **denied** due to nexus with patient safety. DOH will expedite the review of DSRIP projects.

Facility Closure

Regulation: 10 NYCRR 401.3(g)

Nature of Requirement: The regulation at 10 NYCRR 401.3(g) provides that “[n]o medical facility shall discontinue operation or surrender its operating certificate unless 90 days’ notice of its intention to do so is given to the commissioner and his written approval obtained.”

Determination: Waiver requests were **denied**. While DOH 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. In addition, facilities must comply with federal and state statutory notice requirements, such as the federal Worker Adjustment and Retraining Notification (WARN) Act.

Consent Form

Nature of Request: Regulatory waivers to permit the use of a common consent form across providers.

Determination: Waivers are not needed. 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.

Nursing Homes-PRI Regulation: 10 NYCRR 400.11(a)

Nature of Requirement: The regulation at 10 NYCRR 400.11(a) governs the assessment of long term care patients and requires Hospital/Community PRI or PRI as well as the SCREEN.

Determination: We cannot waive the SCREEN portion of this regulation or the credentialing requirements for the person who completes the SCREEN, as this is a federal requirement. The Department **will waive** the PRI requirement in 400.11(a), provided that the provider notify, and obtain approval from, the Department for an alternative screening tool.

Order for Home Care by Physician Assistants

Regulation: 10 NYCRR 766.4(a) and (b)

Nature of Requirement: The regulation at 10 NYCRR 766.4(a) provides that the governing authority or operator is required to ensure that an order from the patient's authorized practitioner is established and documented for the health care services the agency provides to certain patients, as further described under this provision. 10 NYCRR 766.4(b) defines an “authorized practitioner” as a doctor of medicine, a doctor of osteopathy, a doctor of podiatry, a licensed midwife or a nurse practitioner.

Determination: Pending

Medicaid Reimbursement for Transportation To Non-Medical Destination Regulation:

Determination: Waiver requests were **denied**. Such programs are not currently covered by the Medicaid transportation benefit. DOH will explore, through Value-based Payment options, incorporating more flexibility for home visits, telemedicine and other services.

Office of Mental Health Regulations

Medicaid Reimbursement for Mental Health Services Provided Off-Site Regulation: 14 NYCRR 599.14

Nature of Requirement: The regulation at 14 NYCRR 599.14

Determination: The waiver requests were **denied**. Per CMS, Medicaid will not reimburse for mental health services provided off-site.

OMH-Public Need and Financial Feasibility

Determination: Waiver requests were **approved**. A site-specific project application is required to be submitted and will be reviewed by OMH for a determination of character/competency and/or any environmental review. The provider will not need to satisfy a determination of public need or financial feasibility.

Office of Alcoholism and Substance Abuse Services

Reimbursement for Substance Use Disorder Services Provided Off-Site

Regulation: 14 NYCRR 822-3.1(b)

Nature of Requirement: The regulation at 14 NYCRR 822-3.1(b) provides that reimbursement is available only for services delivered at a certified site.

Determination: Waiver requests were **approved** contingent upon notification by the PPS of the specific providers, practitioners and services. However, reimbursement for the provision of such services would require a State Plan Amendment (SPA) to the State Medicaid Plan, which is being pursued by OASAS.

Next Steps

- PPSs should submit any additional information as requested by the State
- DSRIP Integrated Services Model Application-submitted by PPS lead
- PPS submit list of providers linked to each approved waiver
- Waiver approval letters will be sent to each provider that was issued a waiver
- Continued dialogue on policy issues

QUESTIONS

?