

THE ROAD TO REGULATORY RELIEF: UNDERSTANDING THE TERRAIN AND MAPPING THE RIGHT COURSE FOR DSRIP REGULATORY WAIVER REQUESTS

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Agenda

- DSRIP and waiver requests: Background
- Statutory framework underlying State's waiver authority
- State's preliminary guidance on waiver requests
- How to make a waiver request
 - ▣ Do I need one?
 - ▣ Elements
 - ▣ How to talk to your PPS lead
- Examples of waiver requests: Will they fly? (Interactive!)
- State Guidance issued: what is it and should it be amended? (Interactive!)

DSRIP & Waiver Requests: Background

- DSRIP
 - ▣ Collaborative & Integrated
 - ▣ Nimble and forward thinking
- Current regulatory environment
 - ▣ Built by siloed, autonomous agencies without regard to how other agencies might be regulating similar topics
 - ▣ Bureaucratic, time-consuming
 - ▣ Example
- DSRIP Project + Current regulations = Failure
- Recognized need for DSRIP Projects to operate with regulatory flexibility

Waiver Request: Statutory Framework

- SFY 14-15 Article VII
- Allow Comm'rs of DOH and O agencies to waive regulatory requirements to allow joint projects under DSRIP
 - ▣ Includes projects relating to capital restructuring pool
- Waivers must avoid duplicating requirements and allow efficient implementation of project.
- Patient safety regulations cannot be waived, nor could waiver create patient safety issue.
- Waiver of regulations cannot exceed life of the project.
- Report to legislature required.

Psst: State Can Authorize Waivers Outside of DSRIP

- Collaborative Care Clinical Delivery Model
 - ▣ Authorize DOH (in consultation w/ OMH) to establish evidence-based collaborative care delivery model in Art. 28 clinics to improve detection of depression, mental or SUD disorders, and integrated treatment. Regulatory waivers can be sought provided that patient safety is not compromised.
- Emergency Regulatory Authority for Co-Location of Services
 - ▣ Allow DOH, OMH, OASAS, OPWDD to issue emergency regulations to implement co-located services
 - ▣ Also emergency regulation authority allowed for Community-Based Behavioral Health Services Reinvestment Program

State's Preliminary Guidance on Regulatory Waiver Requests

- In its DSRIP application, a PPS may request that the State waive certain regulations issued by OMH, DOH, OASAS and/or OPWDD that would impede the PPS's ability to effectively and efficiently implement its DSRIP projects.
- Guidance on types of waivers, e.g.:
 - antitrust,
 - integrated services,
 - CON,
 - prior approval review,
 - operating standards,
 - information sharing,
 - workforce flexibility.

State's Regulatory Waiver Preliminary Guidance: Examples

- State will consider:
 - ▣ Practitioner credentialing streamlining requests
 - ▣ Waiving restrictive regulations on observation bed services.
 - ▣ Waiving certain discharge regulations
 - ▣ Waiving certain construction standards (OMH, DOH, OASAS)
 - ▣ Waiving prior approval and pre-opening surveys for OMH and OASAS facilities
 - ▣ Waiving regulations governing management contracts, revenue sharing and active parent rules.
 - ▣ Requests to waive CON and need methodology requirements

State's Preliminary Guidance on Waiver Requests: Limitations

- Federal law, state statute or both might provide obstacles to a PPS which the regulatory waiver process will not address.
- Examples
 - Expanding nurse-driven protocols: State has limited authority to waive regulations, but that it will introduce a legislative proposal to address.
 - Patient confidentiality statutes: The State cannot waive federal patient confidentiality rules, but will develop a model consent form for PPSs to use with their patients.
 - Home visits:
 - Article 32 home visits: No regulatory relief is available due to federal requirements, but the State will try to address through a State Plan Amendment (SPA).
 - Article 28 home visits: While DOH will entertain requests for these types of visits for persons with chronic illnesses, it must submit a SPA.

State's Preliminary Guidance on Waiver Requests: Limitations, cont.

- Integrated care delivery: The agencies will consider shared space arrangements provided they are subject to a written plan and consistent with federal requirements. Additionally, the State will be introducing regulatory changes to streamline licensure processes.
- Corporate practice of medicine: The State cannot waive this rule, which arises under the Education Law
- Workforce:
 - Federal regulations prohibit allowing NPs or PAs to sign medical orders for home care services in CHHAs and LTHHCPs
 - State legislative changes will be explored to allow advanced home health aides and practice of community paramedicine

How Do I Know if I Need to Request a Waiver?

- Waiver requests will be based on and linked to the PPS projects
- As you work with your PPS's project advisory committee to develop projects, the logistical and regulatory issues and obstacles will become clearer

How to Make a Waiver Request: Elements

- Should be submitted with the DSRIP application in December.
 - If, however, a PPS determines the need for a waiver after submission of the application later in the DSRIP period, it may submit a request at a later point (maybe – more on this later).
- Waiver requests must:
 - Identify *with specificity* the regulation from which a waiver is being requested.
 - How the regulation impacts specific components of the proposed DSRIP project
 - Why the waiver is needed and how the waiver will result in implementation of the project and reaching better patient outcomes
 - Alternatives to compliance
 - Impact of the waiver on patient safety.
- In considering approval the request, the State may require the applicant to meet certain conditions (e.g., staffing, patient safety, monitoring).

How to Make a Waiver Request: Talking to Your PPS Lead

- Narrow the universe:
 - What are the projects you are involved in
 - What elements are you responsible for delivering?
- Because waiver requests will need to be included in the DSRIP application, you will need to work with your
 - PAC structure to make sure the regulatory obstacles are identified
 - PAC structure to make sure the need for specific waivers are communicated to the Lead
 - PPS Lead to make sure the request waivers are included in the application
- Make it easy – do the work (easier said than done!)
 - Map the project elements to the regulatory obstacles (be specific!)
 - Identify and document whether alternatives to waiver are available or rational
 - Identify whether patient safety issues will be implicated by a waiver
 - Model project timeframes and efficiency with and without the waiver.

Waiver Request Example: Medical Village (2.a.iv)

- Alpha FQHC is participating in creation of a medical village
 - ▣ To achieve this transition, an outdated portion of a hospital will be converted into a space occupied by the FQHC to provide primary and BH services, with extended hours and staffing.

Waiver Request Example: Medical Village (2.a.iv)

- Issues
 - CON
 - Credentialing
 - Shared space with another facility
 - Integration of BH and medical care
 - Possibly
 - Governance
 - Profit-sharing
- DISCUSSION

Waiver Request Example: Integration of Primary Care and Behavioral Health Services (3.a.i)

- Alpha FQHC is also participating in a PPS project to integrate primary care services into established behavioral health sites (clinics and Crisis Centers)
- Core component of project (per DSRIP Project Toolkit):
 - ▣ “With interested community and facility providers, provider will develop structure for integration including governance, MOUs, financial feasibility, and meeting regulatory requirements.”

Waiver Request Example: Integration of Primary Care and Behavioral Health Services (3.a.i)

- Issues
 - CON
 - Shared space with another facility
 - Integration of BH and medical care
 - Governance
 - Profit-sharing
 - Workforce flexibility
- DISCUSSION

Waiver Guidance: Comments?

- Guidance is not proscriptive, but there is language that strongly suggests or states how the State will approach certain ideas.
- CHCANYS is going to provide written comments
- Comment 1: Payment for Threshold Visits
 - ▣ The Guidance did not speak to whether the State would reconsider amending its policy to allow for reimbursement for more than a single service a day. State regulation governing a "threshold visit" imposes the restriction on all clinics.
 - ▣ Impediment to integrated service delivery

Waiver Guidance: Comments

- Comment 2: Waiver process should be ongoing, and not be limited to the DSRIP application.
 - ▣ Likely that necessity of specific regulatory waiver will be more clear as the project implementation plans are developed between December 16 and April 1 and/or the projects begin after April 1
 - ▣ Guidance is not clear on this point
- Other comments?

Conclusion/Questions

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