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Community Health Care Association of New York State www.chcanys.org

DSRIP and Requests for Regulatory Relief

The Delivery System Redesign Incentive Payment (DSRIP) program allows performing provider systems (PPSs) to request from the State waivers of regulations that would impede the PPS's ability to execute on their reform projects. The following document suggests the type of regulatory and policy relief that may be requested, depending on the PPS and its proposed DSRIP projects.

Please note that the regulations identified herein are intended to be illustrative; this is not intended to be an exhaustive list.

Certificate of Need (CON) Regulations and Processes

Many requirements defining actions that trigger a CON review are regulatory. The overarching principle for requesting waiver of CON regulations/requirements is that most, if not all, of the PPSs will engage in activities or transactions that require various levels of CON approval, which can be time consuming and constrictive – particularly if the PPS is engaged in transformative work that does not conform to traditional CON projects.

PPS Public Need and Financial Feasibility Reviews

As a general proposition, the PPS should argue that its component entities should be exempt from separate Public Need and Financial Feasibility reviews (both of which will be covered under State's review of the PPS). 10 NYCRR § 600.1 and Parts 670 and 700.

Assessment of PPS Capital Debt Component

With regard to the assessment of any capital debt component, the State should accept applicant descriptions of terms (rather than letters of interest), and conduct a streamlined review at the loan commitment stage. All loan assessments should be completed by DOH within 15 days of commitment; approvals should be granted no later than 15 subsequent days. 10 NYCRR Parts 600 and 700.

Alignment of CON Approvals and PPS Objectives/Financing

A PPS could request that the State exercise discretion in the use of limited life approvals that may be contrary to meeting the PPS's objectives and financing.

Expediting the CON Process

- *Generally:* The PPS should recommend that the Public Health and Health Planning Council (PHHPC) schedule bi-weekly videoconference meetings to accommodate any required approvals emanating from approved PPSs.

- *Relocations:* Bed and service relocations between established providers in approved PPS should only require letter notification to DOH, and a maximum time frame of DOH approval of 15 days. This recommendation is modeled after 10 NYCRR 708.3. And 708.4 (appropriateness review procedures).
- *Facility and service closures*: A PPS might recommend replacing the 90-day DOH timeline with a maximum 30-day timeline. 10 NYCRR 401.3(g).

Construction projects (including new sites and blending of services licensed by different state agencies)

- *Level of CON review:* The PPS could request that this be limited to architectural review, with a 30-day maximum DOH turnaround. 10 NYCRR Part 600.
- *Self-certification*: Allowing use of self-certification for Architectural and other code compliance could help in expediting PPS projects. 10 NYCRR Part 610.
- *Expediting review*: Imposing a maximum 15-day DOH review for construction start approval. 10 NYCRR Part 600.
- *Pre-opening surveys:* A PPS should request a liberal use of self-certifications and waivers regarding these surveys, and should also request that DOH complete all such surveys within 15-days written notice to DOH. Additionally, a PPS should request that facilities be allowed to open while waivers to non-patient care areas are in process. The pre-opening survey regulation does not impose any timeframe within which DOH to complete the survey. See 10 NYCRR 710.9. The waiver provisions are in 10 NYCRR 711.9.

Multiple Agency Reviews and Approvals. A PPS should request that approvals required from multiple state agencies for the same project should be consolidated into one review process by the state.

Behavioral Health CON Regulations. Specific regulations governing authorization of construction, acquisition or operation of behavioral health facilities or services include the following, which a PPS should consider requesting waiver:

- 14 NYCRR Part 77 (governing physical plant standards for behavioral health facilities)
- 14 NYCRR Part 321 (regarding financing and constructing substance use disorder facilities)
- 14 NYCRR Part 521 (regarding financing assistance for capital construction or acquisition of behavioral health facilities)
- 14 NYCRR Part 551 (regarding expediting project reviews for OMH regulated facilities)
- 14 NYCRR Part 573 (regarding issuing operating certificates to OMH regulated providers)

- 14 NYCRR Part 810 (regarding establishing, certifying substance use disorder services)
- 14 NYCRR Part 814 (regarding OASAS facility requirements)
- 14 NYCRR Parts 620 and 621 (CON Process and financial assistance for construction or other capital projects under OPWDD jurisdiction)
- 14 NYCRR Part 635-6 (Permitted capital costs and transactions with related parties for OPWDD regulated entities)

Regulations that Would Impede Integrated Models

Prohibitions Against Fee-Splitting (10 NYCRR § 600.9). This regulation prohibiting fee splitting or sharing in gross revenues of non-established entities should be waived with respect to the financial components of any agreements dictating the flow of dollars, such as distribution of DSRIP proceeds among PPS providers sharing a patient population.

Co-location. Given the focus of DSRIP on developing integrated delivery systems, particularly addressing integration of behavioral health and medical care, any PPS should request waiver of state regulatory impediments to the co-location of services (i.e., co-locating services licensed by DOH, OMH, OASAS, OPWDD and/ or private practices) to support PPS partnerships and implementation of DSRIP projects. For example, such waivers will ensure redirection away from the ED and reduce hospital admissions through availability of primary and secondary care. Additionally, because not all restrictions against co-location are imposed by the State, a PPS should request that the State petition CMS for the authority to waive its regulations pertaining to the co-location of services when it is deemed to be in the best interests of promoting the objectives of DSRIP. In addition to the CON regulations above, specific regulations that may pose barriers to co-location include:

- 10 NYCRR Part 83 (Shared Health Facilities)
- 14 NYCRR § 814.7 (governing spaces shared with substance use disorder services)
- 14 NYCRR Part 511 (standards and rules around personalized recovery oriented services (PROS))
- 14 NYCRR § 527.6 (rights of behavioral health IP patients to object to treatment)
- 14 NYCRR Part 587 (regarding standards and requirements for operating out patient behavioral health programs, including day treatment, partial hospitalization and other types of programs, and record retention/sharing of such programs)
- 14 NYCRR Part 599 (regarding standards and requirements for clinic treatment programs)
- 14 NYCRR Part 592 (Governing Comprehensive Outpatient Programs)

- 14 NYCRR Part 594 (Governing Operation of Licensed Housing Programs for Children and Adolescents with severe emotional disturbances)
- 14 NYCRR Part 595 (governing operation of residential programs for adults)
- 14 NYCRR Part 816 (governing IP and OP chemical dependence withdrawal and stabilization)
- 14 NYCRR Part 819 (governing standards, operation, staffing for chemical dependence residential services)
- 14 NYCRR Part 822-2 (governing outpatient chemical dependency and opioid treatment)
- 14 NYCRR Part 822-4 (regarding staffing, treatment plans, etc., for outpatient chemical treatment programs)
- 14 NYCRR Part 822-5 (regarding opioid treatment programs)
- 14 NYCRR Part 823 (governing standards, admissions, record keeping treatment plans of chemical dependency OP services for youth)

Data Sharing. There are various regulations that govern and restrict how health and behavioral information can be shared. A PPS should consider the following regulations and how they relate to, support or impede a DSRIP project that involves integrated systems.

- 14 NYCRR Parts 510 & 520 (accessing or correcting OMH records)
- 14 NYCRR Parts 803 & 804 (accessing OASAS records)
- 10 NYCRR §405.10 (Hospital records)
- 10 NYCRR § 751.7 (D&TCs)

Governance Models. Currently, entities and their governance models may be governed under Article 28 of the Public Health Law or Articles 31 or 32 of the Mental Hygiene law. A PPS, or entities' participation in a PPS may require a governance model, or changes to a governance model, that are beyond the scope of the traditional regulatory environment. Accordingly, a PPS or its component entities may choose to request the following types of relief.

- *For un-regulated PPS partners OR a new entity formed for the purpose of serving as the PPS (e.g., "New Company, LLC").* A PPS may ask that DOH only require self-certification of the NewCo PPS. For un-regulated PPS partners in any kind of PPS, a PPS could request that DOH allow self-certification of those partners for appropriate compliance.
- *For a PPS consisting of Article 28s with another regulated entity (Art. 28, 31, and/or 16).* If controlling entity is already established, a PPS might request that DOH limit character and competence review to current board and allow new members or structures to self-certify (attest to character and competence). DOH could reserve the right to audit and subsequently disqualify or modify the entity; and the PPS entity would be held harmless.
- A PPS may desire that powers be controlled and distributed only at parent level;

and may want notification only to DOH. 10 NYCRR § 405.1.

- PPSs should request that the State expedite approvals of required changes to corporate certificates.

Regulations to consider include:

- 10 NYCRR § 405.2 (hospital governing bodies, minimum standards)
- 10 NYCRR Parts 600-670 (Establishment of hospitals)
- 10 NYCRR Part 1001 (Assisted Living)
- 10 NYCRR Part 751 (D&TCs)

Corporate Practice of Medicine. For PPSs with a community-wide practitioner base, corporate practice of medicine rules need to be addressed. To support the development of an effective PPS partnership, state must address how corporate practice of medicine rules will apply to a central governing entity that intends to carry out the role expected by the state. Various provisions of the Education Law and case law apply. *For a comprehensive article on the issue, see "Corporate Practice of Medicine: An Old Doctrine Breathing New Life,"* New York Law Journal *(6/25/2014).*

Paying FQHCs for Multiple Visits in a Single Day

State law does not address the issue of FQHCs being reimbursed for more than a single service a day. Public Health Law Sec. 2807(8). State regulation governing a "threshold visit" imposes the restriction on all clinics (FQHCs or not). The policy is explained in the e-MedNY guidance (https://www.emedny.org/ProviderManuals/Clinic/PDFS/Clinic_Policy_Guidelines.pdf) , excerpted in part, below:

> For Medicaid patients, the basis of payment for most clinic services provided in hospital outpatient departments and diagnostic and treatment centers under Article 28 of the Public Health Law is the threshold visit. New York State Department of Health (DOH) regulation at 10 NYCRR 86-4.9 states:
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> “A threshold visit occurs 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 is allowed for reimbursement purposes, except for transfusion services to hemophiliacs, in which case each transfusion visit constitutes an allowable threshold visit. The visit is all-inclusive as it includes all of the services medically necessary and rendered on that date.
>
> This policy does not apply to those services for which rates of payment have been established for each procedure, such as dialysis and freestanding

ambulatory surgery.

When a Medicaid patient receives treatment(s) during a threshold clinic visit that cannot be completed due to administrative or scheduling problems, the Article 28 facility may not bill additional clinic visits for the completion of the service.

Patient Transitions, Discharges, Transfers

Currently, various agencies have rules and regulations governing patient transitions. These processes must be waived or streamlined in an integrated environment. Regulations to consider include:

- 10 NYCRR §§ 405.9, 400.9, 400.11, 700.3, 415.38
- 18 NYCRR §§ 505.20 and 540.5
- 14 NYCRR § 36.4 and 14 NYCRR § 504.5 (governing community placement after IP behavioral health discharge)
- 14 NYCRR Part 815.7 (regarding discharge from OASAS services)

Long Term Care Regulations

A PPS with long term care service projects should review the following regulations.

- Hospice need requirements and geographic limitations (10 NYCRR Part 790).
- Nursing home regulations, interpreted to protect the safety of other residents that compel nursing homes to transfer patients (especially behavioral patients) to hospitals (*See* 10 NYCRR Part 415).
- Limitations on home care ordering authority (10 NYCRR Part 763).
- Home health aide supervision restrictions (10 NYCRR Part 763).

Anti-Trust

Developing PPSs, forming integrated delivery systems, or even collectively working on a specific DSRIP project may raise anti-trust issues. Currently, the State has not issued any final regulations allowing for PPSs and others to apply for certificates of public advantage (COPAs) or to apply as Medicaid Accountable Care Organizations (ACOs) – both of which would allow for anti-trust protections. Given that these processes are not finalized and entities are not able to apply for such protections, PPSs should request waiver of anti-trust regulations. In addition to state enacted safe harbors, the state must confer state action immunity to shield PPSs from federal antitrust liability.

Management Contracts

Regulatory requirements regarding management contracts may need to be considered for waiver if the management contract vehicle is chosen in PPS formation. A PPS should request waiver of appropriate provisions of the regulations governing approval of Management Contracts when such underlying arrangements are in the best interests of meeting approved PPS objectives. *See, e.g.,* 10 NYCRR §§ 405.3 and 600.9

Workforce

Given DSRIP's requirement that PPSs address workforce issues, as well as provide for innovative care models. A PPS should consider requesting the following relief/State action.

Credentialing. Practitioner credentialing and the ability for practitioners to treat patients throughout a PPS is essential. Effective PPS credentialing will require application of a single system wide credentialing process, and waiver of various state agency requirements. Administrative delays relating to multiple credentialing processes of the State and managed care organizations can impede a PPS's ability to provide access to care, and this is particularly true given that credentialing processes are not tailored to recognize a PPS structure. A PPS should ask the State to develop an expedited single credentialing process that will meet the needs of the PPS and address quality and liability concerns of the State and payers. Regulations to consider include the following:

- 14 NYCRR Part 853 (OASAS Providers)
- 10 NYCRR Parts 94 and 707 (Governing physicians' assistants)
- 10 NYCRR §§ 405.2 and 405.4 (hospitals)

Scope of Practice. Because access to care and cost likely will be issues for any PPS, a PPS should consider requesting DOH work with the State Education Department to address relaxing scope of practice requirements, provided that this does not result compromise patient safety. The State Education Department regulates the professions, including those in the health and social services fields. Regulatory provisions include 8 NYCRR Parts

- 60 (Medical and physicians assistants) (see, e.g., experience requirements in 60.3)
- 61 (Dental and Dental Assistants)
- 64 (Nursing) (see particularly 64.5 and 64.6)
- 72 (Psychology)
- 74 (Social Work)
- 76 (OT) (see, e.g., 76.5 and 76.8)
- 77 (PT)

Provider Licensure. PPS providers are licensed by different state agencies. Therefore, a common set of standards applicable across providers will be needed for effective PPS partnership, which may require waiver of various regulations.

Auditing and Reporting Requirements

PPSs will likely be subject to auditing and reporting requirements from multiple agencies on top of the auditing and reporting requirements specific to DSRIP. A PPS may wish to request waiver of audit and reporting requirements for DSRIP project services other than what is required under the federal waiver. Regulations that may be relevant include:

- 14 NYCRR Part 635-4 (OPWDD)
- 14 NYCRR Part 552 (OMH)
- 14 NYCRR Part 836 (OASAS incident reporting)
- 10 NYCRR Part 86 (DOH audits)
- 10 NYCRR § 400.18 (SPARCS data reporting)
- 10 NYCRR § 751.10 (D&TC adverse event reporting)

Administrative Appeals Processes

With DSRIP projects likely involving providers and services regulated by multiple State agencies, a PPS should consider requesting waiver of duplicative administrative appeals processes in favor of a single, streamlined process. Regulations to consider are listed below.

- 14 NYCRR Part 831 (OASAS administrative appeals)

Behavioral Health Regulations

Consideration should be given to the various regulations in ensuring the coordination of DSRIP integrated care models and regulatory requirements requiring behavioral health care professionals to take certain specific actions relating to provision of medical care.

Consider:

- 14 NYCRR Part 77 (governing physical plant standards for behavioral health facilities)
- 14 NYCRR Part 321 (regarding financing and constructing substance use disorder facilities)
- 14 NYCRR Part 521 (regarding financing assistance for capital construction or acquisition of behavioral health facilities)
- 14 NYCRR Part 551 (regarding expediting project reviews for OMH regulated facilities)
- 14 NYCRR Part 573 (regarding issuing operating certificates to OMH regulated providers)
- 14 NYCRR Part 810 (regarding establishing, certifying substance use disorder services)
- 14 NYCRR Part 814 (regarding OASAS facility requirements)
- 14 NYCRR § 814.7 (governing spaces shared with substance use disorder services)
- 14 NYCRR § 36.4 and 14 NYCRR § 504.5 (governing community placement after IP behavioral health discharge)
- 14 NYCRR Part 815.7 (regarding discharge from OASAS services)
- 14 NYCRR Part 506 (rates and standards relating to intensive case management)
- 14 NYCRR § 507.7 (standards for participation in community based behavioral health services for children)
- 14 NYCRR Parts 510 & 520 (accessing or correcting OMH records)
- 14 NYCRR Parts 803 & 804 (accessing OASAS records)

- 14 NYCRR Part 511 (standards and rules around personalized recovery oriented services (PROS))
- 14 NYCRR § 527.6 (rights of behavioral health IP patients to object to treatment)
- 14 NYCRR Part 587 (regarding standards and requirements for operating out patient behavioral health programs, including day treatment, partial hospitalization and other types of programs, and record retention/sharing of such programs)
- 14 NYCRR Part 599 (regarding standards and requirements for clinic treatment programs)
- 14 NYCRR Part 592 (Governing Comprehensive Outpatient Programs)
- 14 NYCRR Part 594 (Governing Operation of Licensed Housing Programs for Children and Adolescents with severe emotional disturbances)
- 14 NYCRR Part 595 (governing operation of residential programs for adults)
- 14 NYCRR Part 816 (governing IP and OP chemical dependence withdrawal and stabilization)
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- 14 NYCRR Part 822-5 (regarding opioid treatment programs)
- 14 NYCRR Part 823 (governing standards, admissions, record keeping treatment plans of chemical dependency OP services for youth)
- 14 NYCRR Part 831 (OASAS administrative appeals)