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TO: **Memo Distribution List**

FROM: Hinman Straub P.C.

RE: DSRIP Regulatory Flexibility Guidance for Performing Provider Systems

DATE: September 29, 2014

NATURE OF THIS INFORMATION: This information regarding the early stages of developing what will later become new requirements you will need to be aware of or implement. You will likely want to keep abreast of developments or provide your input so the final requirements are not a surprise.

DATE FOR RESPONSE OR IMPLEMENTATION: None- this is for your information.

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THE FOLLOWING INFORMATION IS FOR YOUR FILING OR ELECTRONIC RECORDS:
Category: #2 Providers and payments to them
#3 Plan Management, operations and structure
#9 Medicaid and Medicare Suggested Key Word(s):

On September 19, the Department of Health ("DOH"), Office of Mental Health (OMH), Office of Alcoholism and Substance Abuse Services (OASAS), and the Office for People with Developmental Disabilities (OPWDD) issued a draft ***Regulatory Flexibility Guidance Document*** (hereafter, "Guidance Document") for Performing Provider Systems (PPSs) interested in seeking regulatory waivers in connection with the Delivery System Reform Incentive Payment (DSRIP) Program and the Capital Restructuring Financing Program.

In summary, this memorandum:

- ✓ Provides background on the regulatory waiver process and the broader implications of this process beyond DSRIP;
- ✓ Highlights specific waivers and proposals of interest; and
- ✓ Identifies next steps and additional considerations.

As discussed below, in conjunction with the DSRIP program, the Department is considering a host of waivers to health care regulations as well as changes to what has long been considered fundamental Department of Health policy. This includes exceptions to permit the exercise of active parent powers, revenue sharing (fee splitting), and the delegation of management authority to non-established hospital operators; revisions to CHHA and Hospice need methodology that authorize entities to practice beyond their approved counties; potentially broad waivers for Certificate of Need review for medical facility establishment and construction; the creation of a single, informed consent to allow for the sharing of information between and among all PPS network providers, and a host of significant changes to health care facility operating standards.

The ability to obtain waiver of regulation through the DSRIP process is a unique opportunity for providers that mayhave a lifespan beyond the five year DSRIP time period.. Any requested waivers will be required to be linked to a specific DSRIP project and must also preserve patient safety. Providers are encouraged to communicate with PPS leads to determine which regulatory waivers would be mutually beneficial towards meeting the broad DSRIP goals of healthcare delivery system transformation as well as supporting providers to best meet the needs of the patient population. In addition, as the Department expects to carry forward many changes beyond the DSRIP, it may also be possible to pursue long-sought regulatory revisions by tying them to a particular DSRIP project. Finally, due to the broad scope of regulatory waivers being considered, providers are also encouraged to consider and communicate whether any of the waivers being proposed are operationally problematic.

I. Background

The State has been working with PPSs to determine which regulations, if waived, would help with DSRIP project implementation, and the Guidance Document is intended to serve as a repository of this information based on PPS requests received thus far. As a result, the Guidance Document provides information to PPSs about specific regulations that could be waived (i.e., areas where the Department will "entertain requests") to implement DSRIP projects, and also includes information on:

- policies the State has agreed to waive to implement DSRIP projects;

- examples of waiver requests the State will not grant, either due to policy reasons or because waiver is precluded by superseding Federal or state statutes; and
- waiver requests that are precluded by state and Federal law that the state will nevertheless attempt to achieve through proactive legislation.

The State plans to update the Guidance Document to incorporate additional waiver-related information and has encouraged providers to submit feedback on the Guidance Document and offer other waiver suggestions as soon as possible.

In addition, while the Department's immediate goal remains to use the regulatory waiver process to facilitate DSRIP implementation, the long term goal appears to be to use this process as a tool to effectuate a wide range of regulatory reforms that will continue after DSRIP. Deputy Commissioner of the Office of Primary Care and Health Systems Management at DOH, Dan Sheppard, has indicated that the State will seek to amend the enabling legislation that granted the Agencies the authority to waive regulations for DSRIP, in order to provide flexibility to allow waivers to survive DSRIP and perhaps even extend beyond the scope of DSRIP projects and serve as a tool to accomplish much broader regulatory reform. It is anticipated the State will try to accomplish the legislative changes needed to broaden the scope of its waiver authority in this year's State Budget.

Finally, the Department has stated that it expects PPSs to discuss waiver requests with the State before requesting them in their project plan applications, and the State plans to update the Guidance Document to reflect the addition of any new waiver requests "it will entertain". Waiver requests will be reviewed based on supporting information provided by the PPS in the project plan application. PPSs will also have an opportunity to request additional waivers after they submit their project plan applications to allow PPSs to take advantage of waivers that could be helpful as they begin to implement specific projects.

II. Regulatory Waiver: Scope of Permissible Waivers

Under the enabling legislation, DOH, OMH, OASAS, and OPWDD are authorized to grant waivers of their regulations, as necessary and consistent with applicable law, to avoid duplicative requirements and allow the efficient implementation of DSRIP projects. However, agencies are only permitted to waive regulations that do not relate to or jeopardize patient safety. In addition, all waivers must be (1) project-specific and (2) only exist for the life of the DSRIP project or a shorter period of time as determined by the authorizing commissioner. Waivers also do not automatically apply to all partners within PPS. As mentioned, the State will seek to amend the enabling legislation to allow such waivers to survive the DSRIP.

III. Regulatory Waiver Process

The PPS will make regulatory waiver requests on behalf of its entire network through its project plan application. The project plan application will include specific State requirements that are needed to support the waiver request. These requirements will include, at a minimum, the specific regulation the PPS is requesting to have waived; components of the project affected by the regulation; reasons why the waiver is necessary and how it will assist in implementation and the PPSs ability to achieve better outcomes; a description of proposed alternatives to compliance

with the regulatory standard; and a description of the impact the waiver and implementation of the proposed alternatives would have on patient safety.

As a condition for approval, the State will likely require the PPS to submit specific policies and procedures designed to mitigate any risks attributable to the waiver. The State will also require appropriate staff members to be trained on the policies and procedures and will hold PPSs accountable for compliance with the policies and procedures. PPSs are responsible for ensuring compliance with the waiver and must evaluate the effectiveness of their policies and procedures in mitigating risks caused by the waiver.

IV. Guidance Document Highlights

The document's section on waiver guidance is organized into seven broad categories: (1) PPS Formation; (2) Integrated Services; (3) Certificate of Need; (4) Prior Approval Review; (5) Operating Standards; (6) Information Sharing; and (7) Workforce Flexibility. Highlights from each section are discussed below.

1. PPS Formation Issues

Providers have requested regulatory flexibility to address federal and state antitrust concerns. DOH does not have the authority to waive any regulations in this regard, but the Guidance Document discusses two options that are available to provide antitrust protection—Certificates of Public Advantage (COPA) and certificates of authority to become an Accountable Care Organization (ACO). The Guidance notes that COPAs "will be granted if it appears that the benefits of the collaborative activity outweigh any disadvantages attributable to their anticompetitive effects, and would have the effect of protecting the arrangement from antitrust liability." The Department is also working to finalize draft regulations for ACOs (10 NYCRR Part 1003). Under the State ACO statute, ACOs are entities that are clinically and financially integrated, with mechanisms for shared governance and the ability to negotiate and distribute payment as a single entity. The ACO construct provides "safe harbors" that could protect PPSs from New York's "Corporate Practice of Medicine" prohibition and other Federal and State anti-fraud provisions that prohibit fee-splitting and revenue sharing. Per the Guidance Document, both the corporate practice of medicine and State and Federal anti-fraud statutes are areas where the state either lacks authority or the desire to revise existing law, making the ACO construct valuable, but because its integration requirements will be be too high for most PPSs at this juncture, the COPA is expected to be the more popular option at this time.

2. Integrated Services

The Guidance Document references draft regulations that are being developed (the draft form is available ***here***) to simplify the licensure process for providers who would need to otherwise be licensed by more than one state agency under existing law. These regulations will permit DSRIP providers to offer primary care and behavioral health services under a single license or certification, with the state agency that issues the license or certification responsible for oversight of the provider.

The Guidance Document also addresses requests to share space between health care services. The State will allow shared space pursuant to an approved written plan, provided it is consistent with Federal rules prohibiting shared space (e.g., ESRD services, general hospital, nursing home, FQHC and Ambulatory Surgery Centers).

3. Certificate of Need

By far the most voluminous category, the State has received a number of waiver proposals related to Certificate of Need (CON) to exempt established providers from undergoing the CON process when such changes are sought in connection with DSRIP projects. Members of the Public Health and Health Planning Council have suggested these changes should and will survive the DSRIP. Some of the more significant CON related waivers discussed in the Guidance Document include:

- Projects subject to CON Review: DOH will "consider" waiving 10 NYCRR § 401.3, which relates to review requirements for projects involving changes in physical plant, bed capacity, and the extent and kind of services provided.

- Need Methodology:

    - Medical Facility Establishment and Construction: DOH will entertain requests for waivers for PPSs interested in pursuing waivers under NYCRR Part 670 (Determine of Need for Medical Facility Establishment), 700 (Assessments of Long Term Care Patients, Role of LPNs in providing intravenous therapy) or 709 (Determination of Need for Medical Facility Construction), in order to facilitate PPS activities.

    - CHHAs and LHCSAs: The Department will entertain waiver requests for CHHAs to be able to provide services outside of their approved service area in order to carry out approved DSRIP project plan activities. Members of the PHHPC questioned the Department on this proposal in light of the recent CHHA RFA. Dan Sheppard indicated waiver of CHHA need may require a demonstration from the PPS that there are no CHHAs available in the service area.

    - Hospice: DOH is in the process of reviewing the hospice need methodology and will entertain requests from PPSs interested in waiving hospice need requirements under 10 NYCRR Part 790 to allow hospices to expand their authorized geographic service area.

- Ownership and Management: DOH will entertain requests from PPSs interested in waiving establishment requirements related to the exercise of certain "active parent powers" under 10 NYCRR § 405.1(c). This regulation require entities that exhibit decision-making authority over any of the active parent powers (defined in the regulation) of a hospital to be approved for establishment by the PHHPC. Additionally, DOH will entertain requests from PPSs to waive regulations that prohibit established entities from sharing revenues with non-established providers (10 NYCRR § 600.9 (c)),

as well as regulations that prohibit the governing authority of a hospital from contracting for management services with a party which has not received establishment approval.

- Construction Standards: State agencies will entertain waiver requests for regulations that require facilities to submit separate applications when seeking a waiver of design requirements. Dan Sheppard cautioned these will be difficult to grant as many regulations governing construction standards relate directly to patient safety precautions. In addition, DOH will entertain requests to allow PPSs to expedite or forgo pre-opening survey requirements under 10 NYCRR § 710.9, though for certain newly established D&TCs (ASCs, rural health clinics, and ESRDs) the preopening survey is a Federal requirement and cannot be waived.

4. Prior Approval Review

OMH and OASAS regulations require agency approval prior to allowing changes to health care facilities under a process called Prior Approval Review (PAR). Both agencies will entertain requests for waivers of PAR regulations and other OMH and OASAS regulations related to pre-opening surveys.

5. Operating Standards

The Guidance Document sets forth a number of potential waiver opportunities in this domain.

First, state agencies will entertain requests for waivers relating to admissions, transfers and discharges, including:

- assessments of long term care patients (10 NYCRR § 400.11 and § 700.3);
- transfer and affiliation agreements (10 NYCRR §§ 400.9); admission and discharge (§ 405.9) and long term ventilator dependent residents (10 NYCRR §415.38);
- community placement of patients discharged or conditionally released (14 NYCRR §36.4);
- general hospital discharges (10 NYCRR § 405.9(f)(7); and
- "alternate care" regulations, which prohibit any Medicaid reimbursement from being provided if a patient's initial admission was not both medically necessary and appropriate where the appropriate placement at a lower level of care was not available at the time of admission.

In addition, other operating standard waivers the State will entertain include requests to waive:

- hospital observation service standards, including existing caps on the number of beds and where observation unit beds can be physically located (10 NYCRR § 405.19(g)); and,
- practitioner credentialing requirements, such as, regulations requiring credentialing in hospitals (10 NYCRR §§ 405.2 and 405.4), credentialing for physician assistants (10 NYCRR §§94 and 707), and credentialing for OASAS practitioners (14 NYCRR § 853).

Additionally, DOH has advised that it will amend regulations and revise its Medicaid State Plan to accomplish other PPS requests, including Medicaid reimbursement changes to home visits and potentially similar changes to authorize reimbursement for telehealth services. Medicaid reimbursement is currently not provided for home visits by outpatient departments of D&TCs and general hospitals. The State intends to address this and make such visits Medicaid reimbursable for individuals with chronic illnesses. Further, while the Guidance Document notes the lack of existing regulations governing reimbursement for telehealth services, it does note that OMH and OASAS are developing their own telehealth regulations, and Dan Sheppard indicated that DOH may follow suit with its own telehealth policy. However, unlike home visits, the Guidance Document does not evidence a clear intent to effectuate an affirmative Medicaid reimbursement change.

6. Information Sharing

The State agencies will coordinate on the development of a patient informed consent form for use by the PPS and their providers. The consent would account for all Federal and State requirements and cover all forms of patient information exchanged by providers within the PPS. One member of the PHHPC commented that such information sharing will essentially allow PPSs to become a single provider.

7. Workforce Flexibility

The State *may* pursue regulatory changes to allow physician assistants to issue orders related to the provision of home health care in LHCSAs. The Guidance indicates that the State is interested in allowing Nurse Practitioners and Physician Assistants to be able to issue and sign orders for CHHAs as well, but Federal regulations prohibit this. Dan Sheppard said DOH may try to work through this obstacle.

The Guidance Document provides additional changes DOH will consider but cannot authorize without statutory changes. These include authorizing widespread use of nurse-driven protocols that are consistent with Federal/national standards; amending the Nurse Practice Act in the Education Law to establish Advanced Home Health Aides to carry out medication and perform other advanced tasks; and make changes to emergency medical services to expand training for EMTs and paramedics to be able to provide non-emergent community para-medicine and allow EMS workers to transport patients to alternate destinations for non-acute situations. While no statutory or regulatory waivers, for that matter, are required for the emergency transport proposal, no reimbursement is provided for such alternate transport.

V. Next Steps

The Guidance Document is expected to be revised to incorporate additional information and may undergo several revisions prior to the due date for project plan applications December 16. At this time, PPSs and their network providers are expected to review potential projects and determine where regulatory waivers or proactive legislative changes would be helpful, and engage in a discussion with the Department.

4838-9439-6702, v. 5

REGULATORY FLEXIBILITY GUIDANCE FOR PERFORMING PROVIDER SYSTEMS

September 18, 2014

I. INTRODUCTION

The Department of Health (DOH), the Office of Mental Health (OMH), the Office of Alcoholism and Substance Abuse Services (OASAS), and the Office for People With Developmental Disabilities (OPWDD) are issuing this guidance to Performing Provider Systems (PPSs) interested in seeking regulatory waivers in connection with the Delivery System Reform Incentive Payment (DSRIP) Program and the Capital Restructuring Financing Program, pursuant to Public Health Law (PHL) § 2807(20)(e) and (21)(e).

As PPS plans become more concrete and it appears that there are additional areas where waivers may be appropriate, the agencies will refine this document accordingly.

A. DSRIP

DSRIP, a component of the $8 billion Medicaid Waiver Amendment, will reinvest $6.42 billion over the next five years, beginning April 1, 2015, for the purpose of transforming the State's health care safety net system, reducing avoidable hospital use and achieving other improvements in health and public health, and promoting the sustainability of delivery system transformation by leveraging managed care payment reform. DSRIP providers will collaborate in the submission of DSRIP Project Plan applications as part of PPSs.

PPSs will collaborate on DSRIP projects in four domains:

- Overall Project Progress Projects (Domain 1);
- System Transformation Projects (Domain 2);
- Clinical Improvement Projects (Domain 3); and
- Population-Wide Projects (Domain 4).

Each PPS will employ multiple projects both to transform health care delivery as well as to address the broad needs of the population that the performing provider system serves. Each project will be developed into a specific set of focused milestones and metrics that will be part of the PPS's DSRIP Project Plan.

Earlier this year, the State awarded Design Grant funds that will assist emerging PPSs in designing comprehensive DSRIP Project Plans. On September 29, 2014, DOH will issue, for public comment, the draft DSRIP

Project Plan application, which will be finalized and released on November 14, 2014. Applications will be due on December 16, 2014, with public comment on the applications due in January 2015. Awards will be made in March 2015, and PPSs will start Year 1 of DSRIP implementation on April 1, 2015.

B. Capital Restructuring Financing Program

Pursuant to PHL § 2825, the State will award up to $1.2 billion to support capital projects that will help strengthen and promote access to essential health services. Eligible providers include general hospitals, residential health care facilities, diagnostic and treatment centers and clinics licensed pursuant to the PHL or the Mental Hygiene Law, assisted living providers, primary care providers, and PHL Article 36 home care providers.

The majority of the capital funding will be allocated for projects aligned with the DSRIP Program and applications for capital funding will be submitted along with DSRIP applications.

C. Regulatory Waiver Authority

PHL § 2807(20)(e) and (21)(e) authorizes DOH, OMH, OASAS and OPWDD to waive certain regulatory requirements for DSRIP projects and capital projects that are associated with DSRIP projects. The agencies are authorized to grant such waivers as necessary, consistent with applicable law, to allow 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. Any waivers granted under this authority may not exceed the life of the project or such shorter time periods as the authorizing commissioner may determine.

In accordance with the statutory provisions, waivers must be project-specific and do not automatically apply to all partners within a PPS. In addition, although waivers are intended to facilitate DSRIP Project Plans and are available only for the duration and scope of such plans, they may not be used to establish dual systems of care. Therefore, although DSRIP is a Medicaid initiative, it would be expected that quality improvements and clinical innovations achieved under a Project Plan would be made available to all of a PPS provider's patients.

In addition, only state regulations can be waived – not federal statute or federal regulations or state statute. However, the agencies will consider proposing changes to federal statute or regulations or state statute, as appropriate to facilitate improvements in and sustainability of delivery system transformation. In addition, the agencies will look for opportunities

to pursue regulatory reforms on a more permanent basis, which would apply outside of DSRIP Project Plans.

II. REGULATORY WAIVER PROCESS

As noted, requests for regulatory waivers will be submitted in conjunction with the DSRIP Project Plan application. However, if a PPS later identifies the need for a waiver, a request can be made at that time.

A. Waiver Requests

The DSRIP Project Plan application will include additional detail about the information that must be submitted in support of waiver requests. The type of information that will be requested includes:

- The regulation for which a waiver is being requested;
- Components of the project plan affected by the regulation;
- The reason(s) the waiver is necessary, including an explanation of how a waiver will assist in implementation of the project plan and reaching better health outcomes;
- A description of proposed alternatives to compliance with the regulatory standard for which the waiver is sought; and
- A description of the impact that the waiver and implementation of approved alternatives would have on safety.

B. Waiver Conditions

In approving requests for waivers, DOH, OMH, OASAS or OPWDD may require the applicant to:

- submit policies and procedures designed to mitigate the risk to persons or providers affected by the waiver;
- train appropriate staff on the policies and procedures;
- monitor implementation to ensure adherence to the policies and procedures; and
- evaluate the effectiveness of the policies and procedures in mitigating risk.

If these standards are not satisfied, the State may decline to approve the waiver or, if it has already approved the waiver, may withdraw its approval and require the applicant to maintain compliance with the regulations.

C. Waiver Tracking and Surveillance

The agencies will establish a process to track waivers by provider and facility to ensure that surveyors are aware of approved waivers.

If the survey team determines that the provider has failed to comply with any conditions under which a waiver was granted, the waiver is subject to revocation and the provider could be subject to citations for the underlying regulatory standards.

D. Waiver Reporting

PHL § 2807(20)(e) and (21)(e) provide that the agencies must describe any regulatory relief granted, including each regulation waived and the project to which it relates, in quarterly Medicaid Redesign Team/DSRIP reports provided to the Legislature and made public pursuant to PHL § 2807(20)(c) and (21)(b).

III. AREAS OF GUIDANCE

A. PPS FORMATION

1. Antitrust

PPSs are likely to be interested in any regulatory flexibility that would address federal and state antitrust concerns and facilitate their ability to move forward under DSRIP. While PHL § 2807(20)(e) and (21)(e) do not give the agencies the ability to waive federal and state antitrust laws, DOH is in the process of issuing regulations for Certificates of Public Advantage (COPA) and Accountable Care Organizations (ACOs) pursuant to state laws that offer protections from antitrust liability in certain circumstances. PPSs will be able request that the State provide antitrust immunity through a COPA or an ACO certificate of authority when submitting a DSRIP Project Plan application.

a. Certificates of Public Advantage

PHL Article 29-F sets forth the State's policy of encouraging appropriate collaborative arrangements among health care providers who might otherwise be competitors, if the benefits

of such arrangements outweigh any disadvantages likely to result from a reduction of competition. The statute requires DOH to establish a regulatory structure allowing it to engage in active state supervision as necessary to promote state action immunity under state and federal antitrust laws.

DOH has proposed regulations, 10 NYCRR Subpart 83-1, establishing a process for entities to obtain a COPA pursuant to PHL Article 29-F. A COPA will be granted if it appears that the benefits of the collaborative activity outweigh any disadvantages attributable to their anticompetitive effects, and would have the effect of protecting the arrangement from antitrust liability. In making that determination, DOH will consult with the Office of the Attorney General and, where appropriate, OMH, OASAS and OPWDD, and will seek the recommendation of the Public Health and Health Planning Council. Ongoing, active supervision will be conducted to ensure that the benefits of the collaborative activity continue to outweigh the anticompetitive effects thereof.

The proposed regulations were initially published in the State Register on September 18, 2013, and have been revised in light of public comments received. A Notice of Revised Rulemaking was published in the August 27, 2014 State Register. The revised regulations will take effect upon publication of a Notice of Adoption.

b. Accountable Care Organizations

PHL Article 29-E requires DOH to establish a process for the issuance of certificates of authority for ACOs. An ACO is a voluntary organization of clinically integrated health care providers that work together to provide, manage, and coordinate health care for a defined population, has a mechanism for shared governance and the ability to negotiate, receive, and distribute payments, and is accountable for the quality, cost, and delivery of health care to the ACO's patients. Obtaining a certificate of authority will allow an ACO to take advantage of certain "safe harbors" offering protection from antitrust liability, prohibitions on referral, and limitations on the corporate practice of medicine. Proposed regulations, 10 NYCRR Part 1003, will be published in the State Register in the near future.

2. Corporate Practice of Medicine

PPSs are likely to be interested in making sure that the application of the corporate practice of medicine doctrine does not prevent them from organizing a PPS as contemplated under DSRIP.

However, as noted above, PPSs can seek certificates of authority for ACOs, and under the proposed regulations to be issued, the provision of ACO services shall not be considered the practice of a profession under Title 8 of the Education Law.

3. Fraud and Abuse Statutes

Various federal and state statutory provisions prohibit fee-splitting and revenue sharing, such as the federal Anti-Kickback statute and the prohibition against physician self-referrals in the federal Stark Law and PHL § 238-a. PPSs are likely to be interested in making sure that these types of provisions do not prevent them from distributing funds within the PPS in the manner contemplated under DSRIP.

The ACO regulations define several "safe harbors" that will apply if all other regulatory requirements are satisfied. PPSs can request ACO certificates of authority when applying for DSRIP Project Grants. No regulatory waiver is available.

B. INTEGRATED SERVICES

1. Integration of Services (One Provider)

PPSs are likely to request regulatory waivers which will assist them in their efforts to integrate primary care and behavioral health services.

Generally, to offer both primary care and behavioral health services (meaning mental health and/or substance use disorder services), a provider must be licensed or certified by more than one agency, unless they fall under the applicable "Licensure Threshold."

a. Primary Care Provider Offering Mental Health Services

Currently, a provider licensed under PHL Article 28 and offering primary care services – meaning a general hospital outpatient department or a diagnostic and treatment center ("primary care provider") – and which has more than 2,000

total visits per year must obtain Article 31 licensure by OMH if it provides more than 10,000 annual visits for mental health services or more than 30 percent of its total annual visits are for mental health services, whichever is higher.

b. Primary Care Provider Offering Substance Use Disorder Services

Currently, a primary care provider may not provide substance use disorder services without Article 32 certification by OASAS.

c. Behavioral Health Services Provider Offering Primary Care Services

Currently, a provider licensed by OMH under MHL Article 31 to provide outpatient mental health services or certified by OASAS under MHL Article 32 to provide outpatient substance use disorder services must obtain PHL Article 28 licensure by DOH if more than 5 percent of total visits are for primary care services or if any visits are for dental services.

d. Mental Health Services Provider Offering Substance Use Disorder Services and Substance Use Disorder Services Provider Offering Mental Health Services

Programs licensed or certified by either OMH or OASAS are able to integrate mental health and substance use disorder services with certain limitations pursuant to a Memorandum of Agreement between the two state agencies.

In order to facilitate the integration of primary care and behavioral health services, DOH, OMH and OASAS are working to integrate and simplify the licensure process for providers that exceed the Licensure Thresholds, which would otherwise need to be licensed by more than one agency. The agencies are working on regulatory changes to achieve this.

To facilitate the ability of PPSs to comprehensively address the health and behavioral health concerns of patients, DOH, OMH and OASAS will permit DSRIP providers to offer primary care and behavioral health services under a single license or certification issued pursuant to the Public Health Law or the Mental Hygiene Law. The state agency that issued the license or certification will be responsible for oversight of the provider. Oversight will be based on compliance with the licensing or certifying agency's

standards and the enumerated scope of the particular DSRIP project. To obtain this authority, providers will have to demonstrate that they are in good standing, have adequate staffing plans and sufficient space, and their practitioners will act within their respective scope of practice.

2. Shared Space (Two or More Providers)

PPSs are likely to be interested in pursuing waivers so that multiple providers could share the same licensed physical space.

Currently, OMH regulations allow Article 31 providers to share space with any other provider licensed or certified by OMH, OASAS or DOH, pursuant to a written plan approved by OMH. Similarly, OASAS regulations allow Article 32 providers to share space with any other providers licensed or certified by OASAS, OMH or DOH, to share space pursuant to a plan by OASAS.

Under federal regulations, general hospitals, nursing homes, and clinics offering End Stage Renal Disease (ESRD) service may not share space with any other providers. Further, diagnostic and treatment centers with federal designations such as ambulatory surgery centers and FQHCs are prohibited by federal law from mixing functions and operations in a common space during concurrent or overlapping hours of operations.

In addition to the federal rules, pursuant to 10 NYCRR 401.2(b), an operating certificate shall be used only by the established operator for the designated site of operation, except that the commissioner may permit the established operator to operate at an alternate or additional site approved by the commissioner on a temporary basis in an emergency. Currently, DOH requires Article 28 facilities be separate and distinct from other provider types (e.g., the facility must be a separate, identifiable entity and must be physically, administratively and financially independent and distinct from other operations of any other provider or health facility).

Under 10 NYCRR 401.3(d), the governing authority or operator of a medical facility to whom a current operating certificate has been issued is prohibited from leasing or subletting all or a portion of the facility, unless such facility, its operation, and the service performed conform to and comply with other pertinent provisions required of medical facilities.

To facilitate the integration of services, DOH, OMH and OASAS will allow shared space pursuant to an approved written plan,

consistent with federal rules. However, all licensed providers will be held accountable for complying with all applicable regulatory standards. Potentially, some of these standards, particularly those pertaining to physical plant requirements, could be waived under PHL § 2807(20)(e) and (21)(e), consistent with federal rules, as discussed further below.

It should be noted that when tax-exempt bonds are used to finance construction of a non-profit health facility, the sharing of that facility's space will necessitate approval of the financing authority/lender and providers should consult bond counsel.

C. CERTIFICATE OF NEED

The Certificate of Need (CON) program governs the establishment, ownership, construction, renovation and changes in service of specific types of health care facilities, including:

- General hospitals, nursing homes and clinics (PHL § 2801-a);
- Certified home health agencies (CHHAs) (PHL § 3605); and
- Hospices (PHL § 4004).

CON approval is needed from PHHPC and/or DOH prior to:

- Establishing and/or constructing new facilities, agencies, programs or hospices;
- Renovating existing facilities, agencies, programs or hospices;
- Acquiring major medical equipment;
- Adding or deleting services;
- Changing ownership of facilities, agencies, programs or hospices; and
- Modifying service areas for agencies or hospices.

1. Projects Requiring CON Review

PPSs are likely to be interested in pursuing waivers to exempt established providers from having to undergo the CON process for proposed changes in capacity or the type of services provided, when such changes are sought in connection with DSRIP projects.

Until recently, a general hospital or diagnostic and treatment center (D&TC) would need to submit a CON application if it wanted to add to or remove from its operating certificate any one of up to 60 types of outpatient services. Based upon a recommendation of PHHPC, DOH has reduced the number of outpatient services that trigger review to 22.

To afford additional flexibility as necessary to promote efficient implementation of DSRIP projects, DOH will entertain requests for waivers of CON regulations pursuant to its authority under PHL § 2807(20)(e) and (21)(e). For example, DOH would consider granting waivers of 10 NYCRR § 401.3 (pertaining to changes in physical plant, bed capacity and the extent and kind of services provided).

2. Need Methodology

Various DOH regulatory provisions set forth the methodologies used to determine public need as part of the establishment and construction processes. These include 10 NYCRR Parts 670 (medical facility establishment), 700 and 709 (medical facility construction), 760 (CHHA establishment) and 790 (hospice).

PPSs are likely to be interested in pursuing waivers of such regulations in order to facilitate implementation of DSRIP project plans.

a. Medical Facilities

PPSs are likely to be interested in pursuing waivers of 10 NYCRR Part 670, 700 or 709 in order to facilitate PPS activities. For example, a PPS may assert that it is necessary to obtain an item of medical equipment in order to advance specific clinical objectives under one of its DSRIP projects. In such a case, the approval of that project plan should substitute for a separate public need analysis, and DOH therefore could waive the regulatory methodology.

Pursuant to its authority under PHL § 2807(20)(e) and (21)(e), DOH will entertain requests for waivers of 10 NYCRR Parts 670, 700 and 709 on a case by case basis, and will grant them to the extent necessary for a PPS to carry out approved DSRIP project plan activities.

b. CHHAs

PPSs are likely to be interested in pursuing waivers of 10 NYCRR Part 760 to allow a CHHA that is a member of a PPS to extend its service area beyond that reflected in its operating certificate, so it can provide services throughout the geographic area served by the PPS.

DOH will entertain requests for waiver of the need methodology for CHHAs in order to allow a CHHA to provide services outside of the service area reflected in its operating certificate for the purpose of carrying out approved DSRIP project plan activities.

c. LHCSAs

PPSs are likely to be interested in pursuing waivers of applicable regulations to allow a Licensed Home Care Services Agency (LHCSA) that is a member of a PPS to extend its service area beyond its approved service area so it can provide services throughout the geographic area served by the PPS.

While establishment of LHCSAs requires DOH approval, DOH regulations do not set forth a formal need methodology for their establishment. Therefore, there are no regulations to be waived in order to allow expansion of a LHCSA's service area. However, LHCSAs may expand their approved service areas with DOH approval, and DOH will approve such requests as necessary to allow LHCSAs to carry out approved DSRIP project plan activities.

d. Hospice

PPSs are likely to be interested in pursuing waivers of the hospice need methodology set forth in 10 NYCRR Part 790 in order to expand the geographic areas in which they are authorized to operate.

DOH will entertain requests for waivers of the relevant sections of 10 NYCRR Part 790 on a case by case basis, and will grant them to the extent necessary for a PPS to carry out approved DSRIP project plan activities.

In addition, in conjunction with a PHHPC recommendation, DOH is already in the process of reviewing the hospice need methodology to determine whether amendments to the regulations are necessary.

3. Ownership and Management

a. Active Parent

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).

PPSs are likely to be interested in waiving this provision to the extent it restricts the PPS lead agency or other providers within the PPS from establishing an internal structure for purposes of implementing their Project Plans. Pursuant to its authority under PHL § 2807(20)(e) and (21)(e), DOH will entertain requests for waivers of 10 NYCRR § 405.1(c).

b. Revenue Sharing

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."

PPSs are likely to be interested in pursuing waivers of this provision in order to permit distribution of DSRIP proceeds between PPS established and non-established providers sharing a patient population.

Pursuant to its authority under PHL § 2807(20)(e) and (21)(e), DOH will entertain requests for waivers of 10 NYCRR § 600.9(c).

c. Management Contracts

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 § 403.5(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.

PPSs are likely to be interested in waivers of these regulations so that PPSs can move quickly to carry out their project plans.

Pursuant to its authority under PHL § 2807(20)(e) and (21)(e), DOH will entertain requests for waivers of 10 NYCRR §§ 403.5(f) and 600.9(d) on a case by case basis, and will grant them to the extent necessary for a PPS to carry out the collaborative activities required under DSRIP.

4. Construction Standards

PHL § 2802 requires the Commissioner's approval for construction of a hospital; PHHPC review is required in some cases but not others, as set forth in regulation. DOH regulations require health care facilities to be maintained in compliance with the National Fire Protection Association Life and Safety Code, the Facility Guidelines Institute's (FGI) Guidelines for Design and Construction of Hospitals and Outpatient Facilities, the FGI's Guidelines for the Design and Construction of Residential Health, Care, and Support Facilities and DOH-specific rules for the design of facilities.

For example:

- 10 NYCRR § 712-2.4 (general hospital construction);
- 10 NYCRR § 713-4.3, 713-4.4, 713-4.9 and 713-4.10 (nursing home construction);
- 10 NYCRR § 714.4 (adult day health care program);
- 10 NYCRR § 715-2.4 (ambulatory medical facilities);
- 10 NYCRR § 717.2 (hospice);
- 14 NYCRR §§ 599.5 and 599.12 (OMH clinic construction); and
- 14 NYCRR §§ 814.2, 814.3, 814.6 and 814.7 (OASAS facility construction).

PPSs are likely to be interested in pursuing waivers of regulations that require facilities to submit a separate application when seeking a waiver of design requirements.

Pursuant to their authority under PHL § 2807(20)(e) and (21)(e), DOH, OMH and OASAS will entertain requests for waivers of these sections to the extent patient safety concerns are not implicated and the waivers are consistent with federal rules.

5. Pre-Opening Surveys

PPSs are likely to be interested in pursuing waivers that allow them to forego or expedite pre-opening surveys, which are required after completion of a construction project pursuant to 10 NYCRR § 710.9.

DOH will entertain requests for waivers of 10 NYCRR 710.9 on a case by case basis, and will grant them to the extent it does not implicate patient safety. However, certification surveys that are required of new providers applying for federal designation of facilities such as ambulatory surgery centers, rural health clinics and end stage renal disease facilities are separate from pre-opening surveys and cannot be waived.

D. PRIOR APPROVAL REVIEW

1. Prior Approval Review Process

OMH and OASAS require agency approval prior to allowing changes to health care facilities. OMH regulations subject projects and construction related to mental health programs to Prior Approval Review (PAR). Projects must undergo a comprehensive review if they meet one of several criteria, including if capital costs are $600,000 or greater.

Other projects undergo an E-Z PAR review whenever there is an establishment of a new satellite program or a significant increase in a facility's caseload, among other circumstances. Similarly, OASAS subjects projects in substance use disorder facilities to two different levels of review.

PPSs are likely to be interested in pursuing waivers related to the PAR process in order to facilitate implementation of DSRIP project plans.

To afford additional flexibility as necessary to promote efficient implementation of DSRIP projects, OMH and OASAS will entertain requests for waivers of PAR regulations pursuant to its authority under PHL § 2807(20)(e) and (21)(e). For example, OMH would consider granting waivers to sections of 14 NYCRR Part 551 (pertaining to prior approval review for quality and appropriateness) and OASAS would consider granting waivers to sections of 14 NYCRR Part 810 (pertaining to establishment, incorporation and certification of providers of chemical dependence services).

2. Pre-Opening Surveys

PPSs are likely to be interested in pursuing waivers that allow them to forego or expedite pre-opening surveys, which are required after construction.

Pursuant to its authority under PHL § 2807(20)(e) and (21)(e), OMH and OASAS will entertain requests for waivers of these sections as appropriate, except in the case of MHL bonded properties. In addition, OMH and OASAS will consider self-certification for pre-opening surveys and will provide a streamlined review of design changes in conjunction with DSRIP projects.

E. OPERATING STANDARDS

1. Admission, Discharge and Transfer

PPSs are likely to be interested in pursuing waivers of regulations pertaining to admission, discharge and transfer in order to ease the transitioning of patients between care levels. For example:

- 10 NYCRR §§ 400.9 (transfer and affiliation agreements), 400.11 and 700.3 (assessment of long term care patients), 405.9 (admission and discharge) and 415.38 (long term ventilator dependent residents);
- 18 NYCRR § 505.20 (alternate care);
- 14 NYCRR § 36.4 (community placement of patients discharged or conditional release) and 14 NYCRR § 504.5 (community placement after behavioral health discharge); and
- 14 NYCRR Part 815.7 (discharge from OASAS services).

Pursuant to its authority under PHL § 2807(20)(e) and (21)(e), DOH, OMH and OASAS will entertain requests for waivers of such regulations on a case-by-case basis, to the extent such waivers are not inconsistent with any applicable federal or state statutory requirements.

a. Transfer and Affiliation Agreements

PPSs are likely to be interested in pursuing waivers of 10 NYCRR § 400.9, which governs transfer and affiliation agreements.

Pursuant to its authority under PHL § 2807(20)(e) and (21)(e), DOH will entertain requests for waivers of such regulations on a case-by-case basis, to the extent such

waivers are necessary to facilitate implementation of DSRIP project plans.

b. Assessment of Long Term Care Patients

PPSs are likely to be interested in pursuing waivers of 10 NYCRR §§ 400.11 and 700.3, which govern assessment of long term care patients.

DOH could waive these regulations without the authority of PHL § 2807(20)(e) and (21)(e), as the regulations themselves authorize DOH to waive the requirements thereof for demonstration projects. DOH will entertain requests for such waivers in connection with DSRIP project plans, but only to the extent consistent with federal requirements including the Preadmission Screening and Resident Review (PASRR) process, and contingent upon demonstration of policies and procedures that will ensure appropriate assessment and placement post discharge.

c. General Hospital Discharges

10 NYCRR § 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."

PPSs are likely to be interested in pursuing waivers of this regulation on grounds that the "source of payment" reference could be interpreted as applying to DSRIP funding, and thus could prevent hospitals within a PPS from transferring patients as contemplated under the PPS's DSRIP project plan.

Pursuant to its authority under PHL § 2807(20)(e) and (21)(e), DOH will entertain requests for waivers of 10 NYCRR § 405.9(f)(7) to avoid this result.

d. Alternate Care

18 NYCRR § 505.20 provides that no Medicaid reimbursement is available if a patient's initial admission was not both medically necessary and appropriate but was made because an appropriate placement at a lower level of care was not available at the time of admission.

PPSs are likely to be interested in pursuing waivers of this regulation in cases where an individual is ready to be transitioned from a general hospital or nursing home but there is no placement immediately available in order to allow the facility to continue to receive reimbursement until the individual is appropriately discharged.

The regulation reflects federal Medicaid requirements and cannot be waived pursuant to PHL § 2807(20)(e) and (21)(e).

e. Observation Services

10 NYCRR 405.19(g) establishes standards for the provision of hospital observation services consistent with federal Medicare requirements.

PPSs are likely to be interested in pursuing waivers of DOH limits on the number of observation beds to 5 percent of a hospital's certified bed capacity, requirements that observation units be in a distinct physical space, and approval for the construction of such units. DOH already affords some flexibility as provided for in guidance distributed in April 2013 regarding the use of distinct physical space.

To provide additional flexibility, DOH will entertain requests for waivers of any applicable regulation on a case-by-case basis, to the extent such waivers are not inconsistent with federal requirements.

f. Practitioner Credentialing

Several regulations require practitioners to be credentialed, such as:

- 10 NYCRR §§ 405.2 and 405.4 (credentialing in hospitals);
- 10 NYCRR §§ 94 and 707 (credentialing for physician assistants); and
- 14 NYCRR 853 (credentialing for OASAS practitioners).

PPSs are likely to be interested in simplifying credentialing processes for all practitioners who care for patients throughout the PPS.

Pursuant to its authority under PHL § 2807(20)(e) and (21)(e) and subject to the general conditions discussed above, DOH will entertain requests for waivers of 10 NYCRR §§ 405.2 and 405.4 pertaining to credentialing in order to facilitate DSRIP projects.

2. Home Visits

a. Article 28

10 NYCRR § 401.2(b) provides that an operator may use an operating certificate only for the designed site of operation (except where the Commissioner authorizes temporary operation at an alternate site due to an emergency).

PPSs are likely to be interested in pursuing a waiver for 10 NYCRR § 401.2(b) to allow practitioner home visits for all outpatient departments of general hospitals and D&TCs, which currently is permitted for FQHCs.

Pursuant to its authority under PHL § 2807(20)(e) and (21)(e), DOH will entertain requests for a waiver of § 401.2(b) to allow individuals with chronic illnesses to be visited at home. However, to permit Medicaid reimbursement for such services, DOH would need to amend 10 NYCRR §§ 86-4.9, 86-8.14 and 401.2, and submit to CMS an amendment to New York's Medicaid State Plan (SPA). This cannot be accomplished through a waiver; however, DOH is considering new regulations and a SPA amendment to achieve this.

b. Article 31 Home Visits

Currently, OMH providers can bill on a fee-for-service basis for offsite crisis visits. PPSs are likely to be interested in pursuing waivers so that they can also provide home visits on a non-emergency basis.

Pursuant to its authority under PHL § 2807(20)(e) and (21)(e), OMH will entertain requests for a waiver to allow individuals with mental illnesses to be visited at home. However, to permit Medicaid reimbursement for such services, OMH and DOH would need to amend regulatory provisions. This cannot be accomplished through a waiver; however, DOH is considering new regulations to achieve this. Additionally, OMH would need to submit a SPA

amendment to CMS. OMH is considering new regulations to achieve this.

c. Article 32 Home Visits

14 NYCRR Parts 822 (general service standards for chemical dependence outpatient and opioid treatment programs) and 841 (Medicaid reimbursement for chemical dependence services) pertain to billing for off-site services. PPSs are likely to be interested in pursuing regulatory waivers in order to facilitate their ability to provide home visits and to receive Medicaid reimbursement therefor.

No regulatory waiver is available due to federal requirements, but OASAS is submitting a SPA to move OASAS services to the rehabilitation option of the State Medicaid Plan, which would allow federal participation for off-site services.

3. Telemedicine/Telehealth

PPSs are likely to request regulatory waivers in order to facilitate their ability to carry out DSRIP projects involving telemedicine and/or telehealth.

Authorizing reimbursement for telemedicine/telehealth beyond existing provisions cannot be accomplished through regulatory waivers, as there are no applicable regulations Therefore, no waivers are available pursuant to PHL § 2807(20)(e) and (21)(e).

OMH is in the process of issuing proposed regulations that would permit the use of telepsychiatry in Article 31 clinics, and is developing associated clinical and technical standards as well as billing procedures.

OASAS is working with DOH to develop the ability for OASAS programs to use telemedicine in its Article 32 clinics.

F. INFORMATION SHARING

PPSs are likely to be interested in pursuing regulatory waivers that would assist PPS providers in providing services to patients for purposes of diagnostic, treatment and care management at multiple points throughout the PPS without having to obtain separate consent forms for a patient at each point. For example:

- 10 NYCRR § 415.3(d)(1) (nursing home residents have the right to "personal privacy and confidentiality of his or her personal and clinical records which shall reflect… the resident's right to approve or refuse the release of personal and clinical records to any individual outside the facility except when: (a) the resident is transferred to another health care institution; or (b) record release is required by law;") and

- 10 NYCRR § 751.9(n) (diagnostic and treatment center patients have the right to "approve or refuse the release or disclosure of the contents of his/her medical record to any health-care practitioner and/or health-care facility except as required by law or third-party payment contract");

- 10 NYCRR §§ 763.2(a)(10) and 766.1(a)(11) (home care patients have the right to "privacy, including confidential treatment of patient records, and refusal of their release to any individual outside the agency except in the case of the patient's transfer to a health care facility, or as required by law or third party payment contract"); and

- 10 NYCRR § 794.1(a)(10) (hospice patients have the right to "confidential treatment of patient/family records, and may approve or refuse their release to any individual outside the hospice except in the case of the patient's transfer to a health care facility, or as required by law or third-party payment contract").

The Health Insurance Portability and Accountability Act (HIPAA) allows providers to disclose patient information to other providers for treatment, payment or health care operations. However, other provisions of HIPAA as well as other federal and state statutory provisions contain confidentiality provisions that will restrict patient information sharing within a PPS. For example, federal regulations require patient consent for disclosure of substance use disorder information from certain providers, and OASAS has no ability to waive this requirement. See 42 C.F.R. § 2.31. State law also imposes confidentiality requirements upon protected health information in general as well as HIV and mental health information. Pursuant to MHL § 33.13, OMH providers can only exchange information with other treatment providers without consent for treatment purposes if those providers are licensed or funded by OMH, or if there is an agreement with OMH to do so.

Because patient consent issues are governed by HIPAA and state confidentiality statutes, there is no ability to waive regulations under PHL § 2807(20)(e) and (21)(e). However, DOH, OMH and OASAS will coordinate on the development of a model consent form for use by PPS providers that would cover all forms of patient information exchanged by providers.

G. WORKFORCE FLEXIBILITY

1. Home Care Orders by NPs and PAs

PPSs are likely to be interested in pursuing regulatory changes to allow physician assistants (PAs) to issue orders related to the provision of home health care in LHCSAs. At the same time, they are likely to be interested in pursuing regulatory changes that would broaden home care ordering authority to NPs and PAs to issue and sign orders for home care in CHHAs.

Current state regulation for LHCSAs allows nurse practitioners (NPs) to issue and sign orders for home health care. State regulations for LHCSAs could be amended to also allow physician assistants to sign orders as well. The proposed change to state regulation would take 9-12 months. PAs could be allowed to sign medical orders for home care as the function of PAs is similar to the function of NPs. DOH may pursue regulatory changes to allow PAs to sign orders for LHCSAs.

However, federal regulations do not allow NPs or PAs to sign medical orders for CHHAs and LTHHCPs. So it would not be possible to allow NPs or PAs to sign medical orders for home care services in CHHAs and LTHHCPs. No waiver is available pursuant to its authority under PHL § 2807(20)(e) and (21)(e).

2. Nurse-Driven Protocols

Under current law, a physician or certified NP can prescribe, and nurses can implement, standing orders for four categories of "regimens": administering immunizations; emergency treatment of anaphylaxis; administering purified protein derivative (PPD) tests; and administering HIV tests. Under federal regulation, NPs can prescribe and nurses can implement a more broad range of regimens.

PPSs are likely to be interested in pursuing waivers to authorize widespread use of nurse-driven protocols, consistent with federal/national standards and utilizing evidence-based strategies for disease management.

DOH cannot authorize nurse-driven protocols pursuant to its authority under PHL § 2807(20)(e) and (21)(e), as statutory changes would be needed. DOH will consider developing a legislative proposal to achieve this.

3. Advanced Home Health Aides

PPSs are likely to be interested in pursuing waivers to authorize certain home health aides to administer medications.

The Governor has previously submitted legislation to establish a classification of Advanced Home Health Aides who would be authorized to administer medication and carry out other advanced tasks. DOH recently convened a workgroup to provide guidance on advanced tasks that could be performed by home health aides in home care and hospice settings with appropriate training and supervision, if authorized as an exemption to the Nurse Practice Act in the Education Law. The workgroup's guidance will assist DOH in developing recommendations for a future legislative proposal.

4. Emergency Medical Services

a. Community Paramedicine

At present, PHL Article 30 provides that only a certified emergency medical services (EMS) provider may only care for a patient in response to an emergency.

PPSs are likely to be interested in pursuing regulatory waivers if it could help allow emergency medical technicians (EMTs) and paramedics to provide non-emergent Community Paramedicine.

As indicated, this would not be permissible under PHL Article 30, and because it is statutory in nature it cannot be waived under PHL § 2807(20)(e) and (21)(e). However, DOH will consider recommending legislative changes.

b. Emergency Transport

PPSs are likely to be interested in pursuing regulatory waivers to enable EMS providers to transport of patients to alternate destinations for non-acute situations.

PHL § 3010(3) already permits EMS to allow transport of patients to alternate destinations for non-acute situations, within the confines of the ambulance service's operating certificate, and in fact this is a common practice. Accordingly, no regulatory waiver relief is necessary.

H. OTHER

As previously noted, this document is intended to provide guidance to PPSs to help them prepare to submit DSRIP Project Plan applications. This guidance should be viewed as a starting point and, as PPS plans become more concrete and it appears that there are additional areas where waivers may be appropriate, the agencies will refine this document accordingly.

Pursuant to the authority vested in the Commissioner of Health pursuant to section 2803 of the Public Health Law, the Official Compilation of Title 10 of the Codes, Rules and Regulations of the State of New York ("NYCRR") is amended to add a new Part 404, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

A new Part 404 is added to Subchapter A of Chapter V of 10 NYCRR, to read as follows:

PART 404

INTEGRATED OUTPATIENT SERVICES

§ 404.1 Background and Intent

(a) Physical and behavioral health conditions (i.e., mental illness and/or substance use disorders) often occur at the same time. Persons with behavioral disorders frequently experience chronic illnesses such as hypertension, diabetes, obesity, and cardiovascular disease. These illnesses can be prevented and are treatable. However, barriers to primary care, as well as the difficulty in navigating complex healthcare systems, are a major obstacle to care. Primary care settings have, at the same time, become a gateway to the behavioral health system, as people seek care for mild to moderate behavioral health needs (e.g., anxiety, depression, or substance use) in primary health care settings.

(b) The term "integrated care" describes the systematic coordination of primary and behavioral health care services. Health care providers have long recognized that many patients have both physical and behavioral health care needs, yet physical and behavioral healthcare services have traditionally been provided and paid for separately. The growing awareness of the prevalence and cost of comorbid physical and behavioral health conditions, and the increased recognition that integrated care can improve outcomes and achieve savings, has led to increasing acceptance of delivery models that integrate physical and behavioral health care. Moreover, most patients prefer to have their physical and behavioral health care delivered in one place, by the same team of clinicians.

(c) The purpose of these regulations is to prescribe standards for the integration of physical and behavioral health care services in certain outpatient programs licensed by the Department of Health, the Office of Mental Health, and/or the Office of Alcoholism and Substance Abuse Services.

§ 404.2 Legal Base

(a) Office of Mental Health.

(1) Section 7.09 of the Mental Hygiene Law grants the Commissioner of Mental Health the power and responsibility to adopt regulations that are necessary and proper to implement matters under his or her jurisdiction.

(2) Section 7.15 of the Mental Hygiene Law charges the Commissioner of Mental Health with the responsibility for planning, promoting, establishing, developing, coordinating, evaluating and conducting programs and services of prevention, diagnosis, examination, care, treatment, rehabilitation, training, and research for the benefit of persons with mental illness. Such law further authorizes the Commissioner to take all actions that are necessary, desirable, or proper to carry out the statutory purposes and objectives of the Office of Mental Health, including undertaking activities in cooperation and agreement with other offices within the Department of Mental Hygiene, as well as with other departments or agencies of state government.

(3) Section 31.04 of the Mental Hygiene Law authorizes the Commissioner of Mental Health to set standards of quality and adequacy of facilities, equipment, personnel, services, records and programs for the rendition of services for adults

diagnosed with mental illness or children diagnosed with emotional disturbance, pursuant to an operating certificate.

(4) Sections 31.07, 31.09, 31.13, and 31.19 of the Mental Hygiene Law authorize the Commissioner of Mental Health or his or her representatives to examine and inspect such programs to determine their suitability and proper operation. Section 31.16 authorizes such Commissioner to suspend, revoke or limit any operating certificate, under certain circumstances.

(5) Section 31.11 of the Mental Hygiene Law requires every holder of an operating certificate to assist the Office of Mental Health in carrying out its regulatory functions by cooperating with the Commissioner of Mental Health in any inspection or investigation, permitting such Commissioner to inspect its facility, books and records, including recipients' records, and making such reports, uniform and otherwise, as are required by such Commissioner.

(6) Article 33 of the Mental Hygiene Law establishing basic rights of persons diagnosed with mental illness.

(7) Sections 364 and 364-a of the Social Services Law give the Office of Mental Health responsibility for establishing and maintaining standards for medical care and services in facilities under its jurisdiction, in accordance with cooperative arrangements with the Department of Health.

(b) Department of Health. Section 2803 of the Public Health Law authorizes the Public Health and Health Planning Council to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the provisions of Article 28 of

the Public Health Law, and to establish minimum standards governing the operation of health care facilities.

(c) Office of Alcoholism and Substance Abuse Services.

(1) Section 19.07(c) of the Mental Hygiene Law (MHL) charges the Office of Alcoholism and Substance Abuse Services with the responsibility to ensure that persons who abuse or are dependent on alcohol and/or substances and their families are provided with care and treatment that is effective and of high quality.

(2) Section 19.07(e) of the MHL authorizes the commissioner of the Office of Alcoholism and Substance Abuse Services to adopt standards including necessary rules and regulations pertaining to chemical dependence treatment services.

(3) Section 19.09(b) of the MHL authorizes the commissioner of Alcoholism and Substance Abuse Services to adopt regulations necessary and proper to implement any matter under his/her jurisdiction.

(4) Section 19.21(b) of the MHL requires the commissioner of Alcoholism and Substance Abuse Services to establish and enforce regulations concerning the licensing, certification, and inspection of chemical dependence treatment services.

(5) Section 19.21(d) of the MHL requires the Office of Alcoholism and Substance Abuse Services to establish reasonable performance standards for providers of services certified by the Office.

(6) Section 19.40 of the MHL authorizes the commissioner of Alcoholism and Substance Abuse Services to issue operating certificates for the provision of chemical dependence treatment services.

(7) Section 32.01 of the MHL authorizes the commissioner of Alcoholism and Substance Abuse Services to adopt any regulation reasonably necessary to implement and effectively exercise the powers and perform the duties conferred by Article 32 of the MHL.

(8) Section 32.07(a) of the MHL authorizes the commissioner of Alcoholism and Substance Abuse Services to adopt regulations to effectuate the provisions and purposes of Article 32 of the MHL.

(9) Section 32.05(b) of the MHL provides that a controlled substance designated by the commissioner of the New York State Department of Health as appropriate for such use may be used by a physician to treat a chemically dependent individual pursuant to section 32.09(b) of the MHL.

(10) Section 32.09(b) of the MHL provides that the commissioner of Alcoholism and Substance Abuse Services may, once a controlled substance is approved by the commissioner of the New York State Department of Health as appropriate for such use, authorize the use of such controlled substance in treating a chemically dependent individual.

(d) Pursuant to section 365-l(7) of the Social Services Law and Part L of Chapter 56 of the Laws of 2012 the Commissioners of the Office of Mental Health, Office of Alcoholism and Substance Abuse Services and Department of Health are jointly authorized to establish operating, reporting and construction requirements, as well as joint survey requirements and procedures for entities operating under the auspices of one or more such agencies in order to integrate the delivery of health and behavioral health services in an efficient and effective manner.

§ 402.3 Applicability

(a) The provisions of this Part shall apply to providers seeking approval to provide integrated care services at a single outpatient site (host site). This includes locations licensed under Article 28 of the Public Health Law as diagnostic and treatment centers, extension clinics as defined in paragraph (g) of section 401.1 of Title 10 or general hospital outpatient programs, Chemical Dependence Outpatient Services certified under Article 32 of Mental Hygiene Law or Clinic Treatment Programs licensed under Article 31 of Mental Hygiene Law.

(b) The standards apply to providers certified or licensed by at least two of the said participating state agencies. The initiative seeks to promote increased access to physical and behavioral health services at a single site and to foster the delivery of integrated services. The services are intended to supplement the care of enrolled clients of the host program who need the additional services. Whenever these standards are utilized, appropriate policy and procedural standards must be in place to ensure safety and welfare of patients and staff.

(c) The requirements of this Part shall be in addition to the requirements of the state agency that licensed or certified the proposed host site.

(d) An integrated service provider shall continue to ensure documentation as required per 18 NYCRR section 504.3, 517.3(b), 518.1(c), and 518.3(b).

(e) Integrated services providers of mental health services shall continue to ensure compliance with 18 NYCRR 505.25.

(f) Integrated services providers of substance use disorder services shall continue to ensure compliance with 18 NYCRR 505.27.

(g) With respect to billing for medical assistance, an integrated service provider shall continue to ensure compliance with 18 NYCRR 540.6(a) and 540.6(e).

§ 402.4 Definitions

For the purposes of this Part:

(a) “Behavioral health care” means care and treatment of mental illness and/or substance use disorders.

(b) “Diagnostic and treatment center” means a medical facility as defined in 10 NYCRR section 751.1 or an extension clinic as defined in 10 NYCRR 401.1(g).

(c) "Governing authority" means the entity that substantially controls the operator or provider of service and to which a state licensing agency has issued an operating certificate. The governing authority is the body possessing the right to appoint and remove directors or officers, to approve bylaws or articles of incorporation, to approve strategic or financial plans for a provider or service, or to approve operating or capital budgets for a provider of services.

(d) “General hospital outpatient program” means a distinct part or unit within a general hospital as defined by section 2801(10) of the Public Health Law through which outpatient services, other than hospital-based ambulatory surgery services, are provided.

(e) “Integrated care services" means the systematic coordination of evidence-based physical and behavioral health care in clinics licensed by one or more state licensing

agencies in order to promote health and better outcomes, particularly for populations at risk.

(f) "Integrated services provider" means a provider holding multiple operating certificates or licenses to provide outpatient services, who has also been authorized by a Commissioner of a state licensing agency to deliver identified integrated care services at a specific site in accordance with the provisions of this Part.

(g) “Medical director” is a physician who is responsible for the medical services provided by the integrated care services program, for the overall direction of the medical procedures provided and the direct supervision of medical staff in the performance of medical services.

(h) “Outpatient services” means clinic services provided by a diagnostic and treatment center or general hospital outpatient program, a mental health clinic licensed pursuant to Article 31 of the Mental Hygiene Law, or a substance disorder clinic licensed pursuant to Article 32 of the Mental Hygiene Law.

(i) “Primary care services” means services provided by a physician, nurse practitioner, or midwife acting within his or her lawful scope of practice under Title VIII of the Education Law and who is practicing in a primary care specialty.

(j) "State licensing agency" means the state agency with statutory authority to license or certify a provider of outpatient services and designated in accordance with the provisions of this Part with responsibility to monitor compliance by an integrated care services program with the provisions of this Part. State licensing agency includes the Department of Health, the Office of Mental Health, or the Office of Alcoholism and

Substance Abuse Services, as applicable.

§ 404.5 Integrated Care Models

Providers of integrated care services programs will be approved and designated to deliver integrated care services as one of the following models:

(a) Primary Care Host Model: Given the recognition that the general health care system can serve as a gateway to the behavioral health care system, treatment for substance use disorder and/or mental illness is integrated into a single outpatient physical health setting. In this model, a diagnostic and treatment center or a general hospital outpatient program shall be the host site and the Department of Health shall be responsible for monitoring compliance by an integrated care services program with the provisions of this Part.

(b) Mental Health Behavioral Care Host Model: Given that persons with mental health disorders frequently have a co-occurring substance use disorder and/or also experience chronic illnesses, treatment for substance use disorder and/or physical health is integrated into a single outpatient mental health setting. In this model, an Article 31 clinic treatment program shall be the host site and the Office of Mental Health shall be responsible for monitoring compliance by an integrated care services program with the provisions of this Part.

(c) Substance Use Disorder Behavioral Care Host Model: Given that persons with substance use disorders frequently have a co-occurring mental health disorder and/or also experience chronic illnesses, treatment for mental illness and/or physical health is integrated into a single outpatient substance use disorder treatment setting. In this model,

an Article 32 chemical dependence outpatient treatment clinic shall be the host site and the Office of Alcoholism and Substance Abuse Services shall be responsible for monitoring compliance by an integrated care services program with the provisions of this Part.

§ 404.6 Organization and Administration

(a) An operator may only promote itself as an integrated services provider if the operator has been properly certified by an appropriate state licensing agency, pursuant to this Part.

(b) Governing Body

(1) The established governing authority or operator shall be legally responsible for the quality of patient care services, for the conduct and obligations of the integrated services provider and for ensuring compliance with all Federal, State and local laws, including the New York State Public Health Law, Mental Hygiene Law, and the Education Law.

(2) In order to achieve and maintain generally accepted standards of professional practice and patient care services, the governing body shall establish, cause to implement, maintain and, as necessary, revise its practices, policies and procedures for the ongoing evaluation of the services operated or delivered by the integrated care services program and for the identification, assessment and resolution of problems that may develop in the conduct of the program.

§ 404.7 Treatment Planning

(a) An integrated service provider offering behavioral health services shall provide treatment planning for each patient. Behavioral health treatment planning is an ongoing process of assessing the behavioral health status and needs of the patient, establishing his or her treatment and rehabilitative goals, and determining what services may be provided by the program to assist the patient in accomplishing these goals. The treatment planning process includes, where appropriate, a means for determining when the patient's goals have been met to the extent possible in the context of the program, and planning for the appropriate discharge of the patient from the program. The treatment planning process is a means of reviewing and adjusting the services necessary to assist the patient in reaching the point where he or she can pursue life goals, without impediment resulting from his or her illness.

(b) Patient participation in treatment planning shall be documented by the signature of the patient or the signature of the person who has legal authority to consent to care on behalf of the patient or, in the case of a child, the signature of a parent, guardian, or other person who has legal authority to consent to health care on behalf of the child, as well as the child, where appropriate, provided, however, that the lack of such signature shall not constitute noncompliance with this requirement if the reasons for non-participation by the patient are documented in the treatment plan. The patient's family and/or collaterals (i.e., significant others) may participate as appropriate in the development of the treatment plan and should be specifically identified in the treatment plan.

(c) Each patient must have a written patient-centered treatment plan developed by the responsible clinical staff member and patient. Standards for developing a treatment plan include, but are not limited to:

(1) For mental health or substance use behavioral care host models, treatment plans shall be completed no later than 30 days after admission. For primary care host models, treatment plans shall be completed no later than 30 days after the decision to begin any mental health and/or substance use services beyond pre-admission assessment.

(2) For services provided to a recipient enrolled in a managed care plan which is certified by the Commissioner of the Department of Health or commercial insurance plan which is certified or approved by the Superintendent of the Insurance Department, treatment plans shall be prepared pursuant to such other plan's requirement as shall apply.

(3) If the patient is a minor, the treatment plan must also be developed in consultation with his/her parent or guardian unless the minor is being treated without parental consent as authorized by Mental Hygiene Law section 22.11.

(4) For patients moving directly from one program to another, the existing treatment plan may be used if there is documentation that it has been reviewed and, if necessary, updated within 14 days of transfer.

(d) The treatment plan should include physical health, behavioral health, and social service needs. In addition, specific consideration of the need for Health Home care coordination should be noted when appropriate.

(e) The treatment plan shall include identification and documentation of the following:

(1) the patient-identified problem areas specified in the admission assessment;

(2) the treatment goals for these problem areas (unless deferred);

(3) the objectives that will be used to measure progress toward attainment of treatment goals and target dates for achieving completion of treatment goals;

(4) address and identify methods and treatment approaches that will be utilized to achieve the goals developed by the patient and primary counselor;

(5) schedules of individual and group counseling;

(6) each diagnosis for which the patient is being treated at the program;

(7) descriptions of any additional services (e.g., vocational, educational, employment) or off-site services needed by the patient, as well as a plan for meeting those needs; and

(8) the signature of the qualified health professional, or other licensed individual within his/her scope of practice involved in the treatment.

(f) All treatment plans should be reviewed and updated as clinically necessary based upon the patient's progress, changes in circumstances, the effectiveness of services, and/or other appropriate considerations. Such reviews shall occur no less frequently than every 90 days, or the next provided service, whichever shall be later. For services provided to a recipient enrolled in a managed care plan which is certified by the Commissioner of the Department of Health or commercial insurance plan which is certified or approved by the Superintendent of the Insurance Department, treatment plans may be reviewed pursuant to such other plan requirement as shall apply.

(g) Treatment plan reviews shall include the input of relevant staff, as well as the recipient, family members and collaterals, as appropriate. The periodic review of the treatment plan shall include the following:

(1) assessment of the progress of the patient in regard to the mutually agreed upon goals in the treatment plan;

(2) adjustment of goals and treatment objectives, time periods for achievement, intervention strategies or initiation of discharge planning, as appropriate;

(3) an evaluation of physical health status; and

(4) the signature of the qualified health professional, or other licensed individual within his/her scope of practice involved in the treatment.

§ 404.8 Policies and Procedures

An integrated service provider shall have written policies, procedures, and methods governing the provision of services to patients, including a description of each service provided. These policies, procedures, and methods shall be reviewed annually and revised as necessary. They shall address, at a minimum, the following:

(a) admission criteria;

(b) evaluations and treatment plans;

(c) screening for chemical dependence, mental health, and/or physical health issues;

(d) the provision of medical services, including screening and referral for associated physical or behavioral health conditions;

(e) ensuring prompt follow-up action on patients with abnormal test results or physical findings;

(f) identification of specific support and ancillary providers, where appropriate, and methods for coordinating such service delivery;

(g) appropriate transfer and referral procedures to and from other services;

(h) discharge criteria;

(i) procedures for handling patient emergencies and identification of available off-hour emergency services seven days per week, 24 hours per day, including, but not limited to, detoxification, withdrawal and acute psychiatric services;

(j) ensuring that emergency equipment and staff prepared to care for emergencies are provided in accordance with the services provided at the host site, and equipment is maintained in working order;

(k) the continuity of care, including regular participation of all integrated care services staff in case conferences, in-service training and staff meetings;

(l) the prescription and administration of medication which shall be consistent with applicable Federal and State laws and regulations;

(m) discharge criteria;

(n) policies and procedures for investigating, controlling and preventing infections in the host site. The policies and procedures shall include those for:

(1) the isolation of patients with communicable or infectious diseases or patients suspected of having such diseases;

(2) training all personnel rendering care to such patients in the employment of standard infection control techniques;

(3) obtaining periodic reports of nosocomial infections (nosocomial infections shall include an increased incidence or outbreak of disease due to biological, chemical or radioactive agents or their toxic products occurring in patients or persons working in the host site); and

(4) reporting immediately to the regional health director or associate health commissioner for New York City affairs the presence of nosocomial infections and to the city, county or district health officer the presence of any communicable disease as defined in section 2.1 of Title 10 NYCRR (State Sanitary Code);

(o) public health education and screening with regard to tuberculosis, sexually transmitted diseases, hepatitis, and HIV/AIDS prevention and harm reduction; and

(p) the requirement of the mandatory offer of HIV testing in accordance with section 2781-a of Article 27-F of the Public Health Law.

§ 404.9 Integrated Care Services

(a) Physical Health Primary Care Services

(1) *General Principles.* Integrated services providers of primary care services shall effectively meet patient physical health needs by:

(i) providing patient care in a continuous manner by the same health care practitioner, whenever possible;

(ii) appropriately referring to other health care facilities or health care practitioners for services not available;

(iii)identifying, assessing, reporting and referring cases of suspected child abuse or neglect;

(iv) identifying, assessing, reporting and referring cases of suspected or confirmed domestic violence victims;

(v) ensuring that all staff receive education in the identification, assessment, reporting and referral of cases of suspected child abuse or maltreatment and identification and treatment of victims of domestic violence; and

(vi) developing a written plan of treatment which shall be periodically revised, as necessary, in consultation with other health care professionals.

(2) *Provision of Primary Care Services*

(i) All primary care services shall be provided in a manner that safely and effectively meets the needs of the patients served in the integrated care services program.

(ii) Integrated care services programs delivering primary care services must have sufficient staff and appropriate equipment to deliver primary care services.

(iii) Integrated services providers delivering primary care services shall conduct periodic reviews of its integration of primary care services with behavioral health services as part of its overall quality assurance program.

(iv) Integrated services providers delivering primary care services shall assign a medical director to be responsible for the primary care services.

(v) Primary care services provided within the specialty of OB/GYN are limited to routine gynecologic care and family planning provided pursuant to 10 NYCRR 753.

(vi) Primary care services shall not include prenatal care, dental services and ambulatory surgery which includes any procedure that requires more than minimal sedation or local anesthesia, unless specifically authorized by the Department of Health.

(vii) Health care practitioners, or their delegate, shall provide their patient complete and current information concerning his or her diagnosis, treatment and prognosis in terms the patient can be reasonably expected to understand and necessary for the patient to give informed consent prior to the start of any nonemergency procedure or treatment or both. An informed consent shall include, at a minimum, the provision of information concerning the specific procedure or treatment or both, the reasonably foreseeable risks involved, and alternatives for care or treatment, if any, as a reasonable medical practitioner under similar circumstances would disclose in a manner permitting the patient to make a knowledgeable decision. A patient also may refuse treatment to the extent permitted by law and to be fully informed of the medical consequences of his/her action.

(b) Mental Health Services

(1) Integrated services providers of mental health care shall offer each of the following mental health services, to be provided consistent with patients' conditions and needs, and which include:

(i) Outreach;

(ii) Crisis Intervention:

(a) mental health crisis intervention services must be available 24 hours a day/7 days per week.

(b) after hours coverage may be provided directly by the integrated services provider or pursuant to a Clinical Services Contract which must require, at a minimum, that in the event of a crisis, the nature of the crisis and any measures taken to address such crisis are communicated to the primary care clinician or other designated clinician involved in the individual's treatment in the primary care component of the integrated care services program on the next business day.

(iii) Psychotropic medication treatment, including injectable psychotropic medication administration for adult patients;

(iv) Psychotherapy services, including but not limited to:

(a) Family/Collateral psychotherapy;

(b) Group psychotherapy; and

(c) Complex Care Management.

(1) The following optional services may be offered:

(i) Developmental testing (for children and adolescents);

(ii) Psychological testing;

(iii) Psychiatric consultation; or

(iv) Injectable Psychotropic medication administration for patients who are minors.

(2) Notwithstanding 14 NYCRR Part 599, mental health services shall be delivered pursuant to section 404.7 of this Part.

(3) Integrated services providers delivering mental health services shall conduct periodic reviews of the integration of primary care and/or chemical dependence services as part of its overall quality assurance program.

(c) Substance Use Disorder Services

(1) For purposes of this subdivision, the term "clinical staff" shall mean staff who provide services directly to patients as prescribed in the treatment/recovery plan; including licensed medical staff, credentialed or licensed staff, non-credentialed staff, and student interns.

(2) Integrated services providers of substance use disorder services shall offer each of the following services, to be provided consistent with patients' conditions and needs:

(i) Counseling, which can be delivered via two distinct methods:

(a) Individual counseling, which is a face-to-face service between a clinical staff member and a patient focused on the needs of the patient to be delivered consistent with the treatment/recovery plan, its development, or emergent issues. Individual counseling must be provided with a frequency and intensity consistent with the individual needs of each unique patient, as prescribed by the responsible clinical staff member; and

(b) Group counseling, which is a face-to-face service between one or more clinical staff member and multiple patients at the same time, to be

delivered consistent with patient treatment/recovery plans, their development, or emergent issues. Group counseling must contain no more than 15 patients in each group counseling session.

(2) Education about, orientation to, and the opportunity for participation in, available and relevant peer support and mutual assistance groups; and

(3) Chemical abuse and dependence awareness and relapse prevention.

(4) An integrated services provider of chemical dependence services shall:

(i) promote the achievement and maintenance of recovery from chemical dependence and abuse;

(ii) improve functioning and development of necessary recovery management skills so the patient can be treated in the least intensive environment; and

(iii) develop individualized treatment/recovery plans to support the achievement and maintenance of recovery from chemical dependence and abuse, the attainment of economic self-sufficiency (including, where appropriate, the ability to sustain long-term productive employment), and improvement of the patient's quality of life.

(5) Integrated services providers delivering chemical dependence services shall conduct periodic reviews of the integration of primary care and/or mental services as part of its overall quality assurance program.

§ 404.10 Environment

(a) The minimum physical plant requirements necessary for certification for existing facilities to provide integrated care services are described herein. Providers licensed or

certified by a state licensing agency after the effective date of this Part that wish to provide integrated care services or anticipate new construction or significant renovations shall comply with the requirements under Part 711 (General Standards of Construction) and Part 715 (Standards of Construction for Freestanding Ambulatory Care Facilities) of Title 10 of New York Codes, Rules and Regulations.

(b) Outpatient clinic sites proposing to integrate services pursuant to these standards must currently be in compliance with the applicable state licensing agency's environmental standards currently governing the site.

(c) Standards for Integrated Care Services Clinics. In addition to being in compliance with the applicable state licensing agency's environmental standards currently governing the site as required under subdivision (b) of this section, integrated services providers shall meet the following requirements:

(1) General Facility Requirements

(i) A current and accurate floor plan, specifying room locations, dimensions and functions will be provided to each applicable state licensing agency. Program space, except medical examination and treatment rooms, may be shared between certified outpatient services pursuant to an approved schedule. Individual and group rooms should not be utilized for multiple services simultaneously.

(ii) An adequately furnished waiting area shall be available to those waiting for services and shall be supervised to control access to the facility. There should be sufficient separation and supervision of various treatment groups (e.g. children) to ensure safety.

(iii) Programs shall ensure accessibility for person with disabilities, including availability of accessible bathroom facilities.

(iv) Sufficient space for individual and group sessions consistent with the number of people served and the service offered shall be available. Space should afford visual and acoustical privacy for both individuals served and staff.

(v) Programs shall have sufficient and appropriate furnishings and program related equipment and materials for the population served.

(vi) Areas for the proper storage, preparation and use or dispensing of medications and medical supplies and equipment shall be made available. Sharps containers shall be provided and secured, syringes and other supplies should be securely stored, and provisions for holding medical/Red Bag waste are required.

(vii) Programs shall provide for controlled access to and maintenance of records and confidentiality of all patient information.

(viii) Annual inspection and testing of the existing fire alarm system, including battery operated smoke detectors, fire extinguishers, emergency lighting systems, illuminated exit signs and environmental controls and heating/cooling systems shall be conducted.

(ix) Facilities should be maintained in a clean and responsible manner which protects the health and safety of all occupants.

(2) Specific Facility Requirements for Integrating Primary Care Services

(i) Notwithstanding Part 710 (Approval of Medical Facility Construction), Part 711 (General Standards of Construction) and Part 715 (Standards of Construction for Freestanding Ambulatory Care Facilities) of

Title 10 NYCRR, physical plant standards under this sub-clause apply to a behavioral health clinic provider authorized to integrate physical health services with no more than 3 proposed examination rooms for physical health services.

(a) Clean Storage. A separate room or closet for storing clean and sterile supplies shall be provided. This storage shall be in addition to that of cabinets and shelves within the exam rooms or patient treatment areas.

(b) An integrated service provider shall dispose of soiled linens and trash appropriately, either through specially-designated receptacles or separate holding room depending upon the volume of soiled materials generated.

(c) If utilizing a receptacle for soiled linens and trash, such receptacle shall not exceed 32 gallons in capacity and shall meet the following:

(1) The average density of the container capacity in a room or space shall not exceed 0.5 gal/ft sq.

(2) A receptacle with a capacity of 32 gallon shall not exceed any 64 ft sq. area.

(3) Mobile soiled linen or trash collection receptacles greater than 32 gallons shall be located in a room protected as a hazardous area when not attended.

(d) If exceeding 32 gallons in capacity at any given time, the integrated service provider shall maintain a soiled holding room.

(1) Soiled holding is for separate collection, storage, and disposal of soiled materials.

(2) A soiled holding room shall be provided, if a dedicated space cannot be provided in the storage area.

(3) All contaminated materials shall be located and placed in a secured and sealed container and disposed of properly in. This shall be in the dedicated storage space that is secured and access is only by the Limited Service Clinic Staff.

(4) The containers used solely for recycling clean waste or for patient records awaiting destruction outside a hazardous storage area shall be a maximum capacity of 96-gallons. To allow the increase in size of containers used solely for recycling clean waste or for patient records awaiting destruction outside of a hazardous storage area to be a maximum of 96-gallons, but only if the provider/supplier is in compliance with sections 18/19.7.5.7.2 of the 2012 Life Safety Code.

(e) Toilet Rooms

(1) A toilet room containing a hand-washing station shall be accessible from all examination and treatment rooms.

(2) Public Toilet. Toilet(s) for public use shall be immediately accessible to the waiting area. In smaller units (less than four employees), the toilet may be unisex.

(3) Where a facility contains no more than three examination and/or treatment rooms, the patient toilet shall be permitted to serve waiting areas.

(4) Staff toilet and lounge shall be provided in addition to and separate from public and patient facilities.

(5) Centralized staff facilities are not required in small centers. In small centers, staff may utilize shared toilet facilities. Small centers less than four employees.

(6) Floors shall have a smooth, hard, non-absorbant surface that extends upward onto the walls at least 6 inches (152 mm). Vinyl composition tile (VCT) shall not be used in toilet rooms.

(f) Examination and Treatment Rooms

(1) No more than 3 examination rooms shall be provided.

(2) At least one examination room shall be available for each provider who may be on duty at any one time.

(3) Provision shall be made to preserve patient privacy from observation from outside an examination/treatment room through an open door.

(4) A counter or shelf space for writing or electronic documentation shall be provided.

(g) Space Requirements

(1) Each examination/observation room shall have a minimum clear floor area of 80 square feet (7.43 square meters).

(2) The exam room can be a minimum of 72 square feet in size. If other exams rooms are handicap compliant or operational, assistance can be provided by the escort in and out of the exam room.

(3) If three exams rooms are provided, two should be handicap accessible.

(4) Room arrangement shall permit a minimum clear dimension of 2 feet 8 inches (81.28 centimeters) at each side and at the foot of the examination table, recliner, or chair.

(5) The room has to be proportionally designed and clearances maintained in the exam room.

(h) Hand-Washing Stations

(1) A hand-washing station shall be provided in each room where hands-on patient care is provided.

(2) Hand sanitation dispensers shall be provided in addition to hand-washing stations.

(3) Hand-washing basins/countertops shall be made of porcelain, stainless steel, or solid surface materials. Basins shall be permitted to be set into plastic laminate countertops if, at a

minimum, the substrate is marine-grade plywood (or equivalent) with an impervious seal.

(4) Sinks shall have well-fitted and sealed basins to prevent water leaks onto or into cabinetry and wall spaces.

(5) The water pressure at the fixture shall be regulated.

(6) Design of sinks shall not permit storage beneath the sink basin, and should accommodate ADA accessibility standards for clearance under the sink basin as required by Title 28 of the Code of Federal Regulations, Public Health Parts 35 and 36.

(i) Waiting Area

(1) The waiting area for patients and escorts shall be under staff control.

(2) The seating shall contain no fewer than two spaces for each consultation room and no fewer than 1.5 spaces for the combined projected capacity at one time of the group rooms.

(3) Where the psychiatric outpatient unit has a formal pediatrics service, a separate, controlled area for pediatric patients shall be provided.

(4) The waiting area shall accommodate wheelchairs.

(5) Provisions for drinking water shall be available for waiting patients. In shared facilities, provisions for drinking water may be outside the outpatient area if convenient for use.

(j) Corridor Allowed to be Used as a Waiting Area

(1) Fixed furniture in egress corridor. The furniture must be securely attached to the floor or wall and can be on only one side of the corridor. Each grouping of furniture cannot exceed 50 square feet and must be at least 10 feet from other groupings.

(2) Furniture is located so as to not obstruct access to building service and fire protection equipment, such as fire extinguishers, manual fire alarm boxes, shutoff valves, and similar equipment

(3) Corridors throughout the smoke compartment are protected by an electrically supervised automatic smoke detection system, or the fixed furniture spaces are arranged and located to allow direct supervision by the facility staff from a nurses' station or similar space

(4) The smoke compartment is protected throughout by an approved, supervised automatic sprinkler system.

(k) Combustible Decorations in Egress Corridors and Rooms

(1) Combustible decorations are flame-retardant or are treated with approved fire-retardant coating that is listed and labeled for application to the material to which it is applied

(2) The decorations meet the requirements of NFPA 701, Standard Methods of Fire Tests for Flame Propagation of Textiles and Films

(3) The decorations exhibit a heat release rate not exceeding 100 kW when tested in accordance with NFPA 289, Standard Method of Fire Test for Individual Fuel Packages, using the 20 KW ignition source

(4) The decorations, such as photographs, paintings, and other art, are attached directly to walls, ceiling, and non-fire rated doors in accordance with the following:

i. Decorations on non-fire rated doors do not interfere with the operation or any required latching of the door.

ii. Decorations do not exceed 20 percent of the wall, ceiling, or door areas inside any room or space of a smoke compartment that is not protected throughout by an approved automatic sprinkler system.

iii. Decorations do not exceed 30 percent of the wall, ceiling, and door areas inside any room or space of a smoke compartment that is protected throughout by an approved supervised automatic sprinkler system.

(l) Existing openings in exit enclosures to mechanical equipment spaces that are protected by fire-rated door assemblies. These mechanical equipment spaces must be used only for non-fuel-fired mechanical equipment, must contain no storage of combustible materials, and must be

located in sprinklered buildings. This waiver allowance will be permitted only if the provider/supplier is in compliance with all other applicable 2000 LSC exit provisions, as well as with section 7.1.3.2.1(9)(c) of the 2012 LSC.

(ii) Behavioral health clinic providers authorized to integrate physical health services with more than 3 proposed examination rooms shall comply with the requirements under Part 710 (Approval of Medical Facility Construction), Part 711 (General Standards of Construction) and Part 715 (Standards of Construction for Freestanding Ambulatory Care Facilities) of Title 10 NYCRR.

(d) Building Code Requirements

(1) All services and facilities are required to adhere to applicable building codes as well as all local occupancy, use, building and zoning laws.

(2) A valid Certificate of Occupancy is required.

(3) NFPA 101 Life Safety Code, 2000 edition for Chapter 20 New Ambulatory Health Care, Chapter 21 Existing Ambulatory Health Care, Chapter 38 New Business, and Chapter 39 Existing Business occupancies.

(4) New York State Sanitary Code.

(5) All occupied areas shall be ventilated by natural and/or mechanical means.

(6) Air-handling duct systems shall meet the requirements of NFPA 90A.

§ 404.11 Quality Assurance, Utilization Review and Incident Reporting

(a) Quality Assurance

(1) Physical Health Services.

(i) Integrated services providers of physical health care shall ensure the development and implementation of a written quality assurance program that includes a planned and systematic process for monitoring and assessing the quality and appropriateness of patient care and clinical performance on an ongoing basis. The integrated care services program shall resolve identified problems and pursue opportunities to improve patient care.

(ii) The integrated care services program shall be supervised by the medical director. This responsibility may not be delegated.

(iii)There shall be a written plan for the quality assurance program which describes the program's objectives, organization, responsibilities of all participants, scope of the program and procedures for overseeing the effectiveness of monitoring, assessing and problem-solving activities.

(iv)The quality assurance process shall define methods for the identification and selection of clinical and administrative problems to be reviewed. The process shall include but not be limited to:

(a) the establishment of review criteria developed in accordance with current standards of professional practice for monitoring and assessing patient care and clinical performance;

(b) regularly scheduled reviews of medical charts, patient complaints and suggestions, reported incidents and other documents pertinent to problem identification;

(c) documentation of all quality assurance activities, including but not limited to the findings, recommendations and actions taken to resolve identified problems; and

(d) the timely implementation of corrective actions and periodic assessments of the results of such actions.

(v) The scope of clinical and administrative problems selected to be reviewed for the purpose of quality assurance shall reflect the scope of services provided and the populations served at the center.

(vi) The outcomes of quality assurance reviews shall be used for the revision or development of policies and in granting or renewing staff privileges, as appropriate.

(vii) There shall be participation in the program by administrative staff and health-care professionals representing each professional service provided.

(viii) There shall be joint participation in the program by representatives from the behavioral health components of an integrated care services program; such participation shall include, but is not limited to, specific identification of quality improvement opportunities with respect to patient concerns and complaints, changes in regulatory requirements, or other factors, no less frequently than once every two years. Documentation shall be kept of all such reviews.

(ix) The findings, conclusions, recommendations and actions taken as a part of the quality assurance program shall be reported to the operator by the medical director. An annual report shall be submitted to the governing authority, which documents the effectiveness and efficacy of the integrated care services program in relation to its goals and quality assurance plan and indicate any recommendations and plans for improvement it its services to patients, as well as recommend changes in its policies and procedures.

(2) Behavioral Health Services

(i) Integrated services providers of mental health and/or chemical dependence services shall comply with all requirements of 14 NYCRR Part 599 or 822, as applicable, relating to quality assurance.

(ii) Integrated services providers of mental health and/or chemical dependence services shall prepare an annual report and submit it to its governing authority. This report must document the effectiveness and efficiency of the ambulatory care program in relation to its goals and quality assurance plan and indicate any recommendations and plans for improvement in its services to patients, as well as recommended changes in its policies and procedures.

(iii) Utilization review.

(a) Integrated services providers of mental health and/or chemical dependence services shall establish and implement a utilization

review plan. The utilization review plan must include participation by all component providers of the integrated care services program.

(b) Integrated services providers of mental health and/or chemical dependence services may use a utilization review process developed by the state licensing agency or may develop its own utilization review process that is subject to approval by the state licensing agency.

(c) Integrated services providers of mental health and/or chemical dependence services may perform its utilization review process internally; or it may enter into an agreement with another organization, competent to perform utilization review, to complete its utilization review process.

(d) Utilization review must be conducted by at least one clinical staff member. No member shall participate in utilization review decisions relative to any patient he or she is treating directly.

(e) The utilization review plan must include procedures for ensuring that retention criteria are met and services are appropriate. The utilization review plan must consider the needs of a representative sample of patients for continued treatment, the extent of the behavioral health problem, and the continued effectiveness of, and progress in, treatment. At a minimum, utilization review must include separate random samples based upon a patient's length of

stay, with larger samples for patients with longer lengths of stay. Utilization review must also be conducted for all active cases within the twelfth month after admission and every 90 days thereafter.

(f) Documentation of utilization review must be maintained providing evidence that the deliberations:

(1) were based on current progress in treatment relative to the applicable functional areas identified in the patient's comprehensive treatment/recovery plan;

(2) determined the appropriateness of continued stay at the outpatient level of care and intensity of services, as well as whether co-occurring disorder(s) require referral to outside services;

(3) determined the reasonable expectation of progress towards the accomplishment of the goals and objectives articulated in the patient's treatment/recovery plan, based on continued treatment at this level of care and intensity of services; and

(4) resulted in a recommendation regarding continuing stay, intensity of care and/or referral of this case.

(b) Incident Reporting

(1) OMH-host providers shall report incidents involving patients receiving mental health services in accordance with the provisions of 14 NYCRR Part 524.

(2) OASAS-host providers shall report incidents involving patients receiving chemical dependence services in accordance with the provisions of 14 NYCRR Part 836.

(3) DOH-host providers shall report incidents in accordance with the provisions of 10 NYCRR Part 405.6 or 10 NYCRR 751.10, as applicable.

§ 404.12 Staffing

(a) Personnel. The governing authority or operator shall ensure the employment of personnel without regard to age, race, color, sexual orientation, religion, sex or national origin. A personnel file shall be maintained for each employee.

(b) Integrated services programs that are providing primary care services shall ensure that:

(1) the health status of each employee is examined prior to the beginning of employment, which is sufficient in scope to ensure that the employee is free from a health impairment which is of potential risk to patients or which may interfere with the performance of his/her duties;

(2) a record of the following tests, procedures and examinations is maintained for all employees:

(i) a certificate of immunization against rubella which means:

(a) a document prepared by a physician, physician's assistant, specialist's assistant, nurse practitioner, licensed midwife or a laboratory possessing a laboratory permit issued pursuant to Part 58 of

Title 10 of the New York Codes of Rules and Regulations, demonstrating serologic evidence of rubella antibodies;

(b) a document indicating one dose of live virus rubella vaccine was administered on or after the age of 12 months, showing the product administered and the date of administration, and prepared by the health practitioner who administered the immunization; or

(c) a copy of a document described in clause *(a)* or *(b)* of this subparagraph which comes from a previous employer or the school which the employee attended as a student; and

(ii) a certificate of immunization against measles, for all personnel born on or after January 1,1957, which means:

(a) a document prepared by a physician, physician's assistant, specialist's assistant, nurse practitioner, licensed midwife or a laboratory possessing a laboratory permit issued pursuant to Part 58 of Title 10 of the New York Codes of Rules and Regulations, demonstrating serologic evidence of measles antibodies; or

(b) a document indicating two doses of live virus measles vaccine were administered with the first dose administered on or after the age of 12 months and the second dose administered more than 30 days after the first dose but after 15 months of age showing the product administered and the date of administration, and prepared by the health practitioner who administered the immunization; or

(c) a document, indicating a diagnosis of the employee as having had measles disease, prepared by the physician, physician's assistant/specialist's assistant, licensed midwife or nurse practitioner who diagnosed the employee's measles; or

(d) a copy of a document described in clause (a), (b) or (c) of this subparagraph which comes from a previous employer or the school which the employee attended as a student;

(iii) if any licensed physician, physician's assistant/specialist's assistant, licensed midwife or nurse practitioner certifies that immunization with measles or rubella vaccine may be detrimental to the employee's health, the requirements of subparagraph (i) and/or (ii) of this paragraph relating to measles and/or rubella immunization shall be inapplicable until such immunization is found no longer to be detrimental to such employee's health. The nature and duration of the medical exemption must be stated in the employee's employment medical record and must be in accordance with generally accepted medical standards, (see, for example, the recommendations of the American Academy of Pediatrics and the Immunization Practices Advisory Committee of the U.S. Department of Health and Human Services); and

(iv) for all personnel prior to employment or affiliation, except for personnel with no clinical or patient contact responsibilities who are located in a building or site with no patient care services, either tuberculin skin test or Food and Drug Administration (FDA) approved blood assay for the detection

of latent tuberculosis infection, prior to employment or affiliation and no less than every year thereafter for negative findings. Positive findings shall require appropriate clinical follow-up but no repeat tuberculin skin test or blood assay. The medical staff shall develop and implement policies regarding positive outcomes; and

(v) an annual, or more frequent if necessary, health status reassessment to assure freedom from a health impairment which is a potential risk to the patients or might interfere with the performance of duties;

(vi) documentation of vaccination against influenza, or wearing of a surgical or procedure mask during the influenza season, for personnel who have not received the influenza vaccine for the current influenza season, pursuant to section 2.59 of Title 10 of the New York Codes of Rules and Regulations.

(3) each person delivering health care services wears identification indicating his/her name and title.

(c) Medical Director.

(1) Integrated care services programs that are providing primary care services shall have a medical director. The operator or governing authority shall be responsible for appointing a medical director who:

(i) is qualified by training, experience, and administrative ability;

(ii) is a physician licensed by and currently registered with the New York State Education Department;

(iii) develops and recommends to the governing authority or operator policies and procedures governing patient care, medical staff and clinical privileges; and

(iv) is responsible for the supervision of the quality assurance program and reporting to the governing authority or operator.

(2) For integrated services providers of substance use disorder services, such medical director shall:

(i) hold a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties; or

(ii) hold an addiction certification from the American Society of Addiction Medicine; or

(iii) hold a certification by the American Board of Addiction Medicine (ABAM); or hold a subspecialty board certification in Addiction Medicine from the American Osteopathic Association;

(iv) shall possess a Federal DATA 2000 waiver (buprenorphine-certified), provided, however

(v) the program may have a consultation agreement with a full- or part-time physican who meets the requirements of this paragraph, or is exempted therefrom.

§ 404.13 Recordkeeping

(a) An integrated care services record shall be maintained for every individual who is admitted to and treated by an integrated services provider, and this may be accomplished

via a single integrated record for the individual. The integrated care record contents may be maintained in either paper (hardcopy) or electronic formats.

(b) Regardless of form or format, each integrated care services program shall establish a recordkeeping system which is maintained in accordance with recognized and accepted principles of recordkeeping.

(c) Each integrated care services program shall designate a staff member who has overall supervisory responsibility for the recordkeeping system. The recordkeeping supervisor shall ensure that:

(1) the integrated care record for each patient contains and centralizes all physical and behavioral health information which identifies the patient, justifies the treatment and documents the results of such treatment;

(2) entries in the integrated care record are current, legible to individuals other than the author, are authenticated with a signature of the person making the entry, date, and time;

(3) handwritten entries must be made in permanent, non-erasable blue or black ink or typed;

(4) information contained in the integrated care record is securely maintained, kept confidential, safeguarded from environmental damage, and made available only to authorized persons who have a need to know the information; and

(5) when a patient is treated by an outside provider, and that treatment is relevant to the patient's care, a clinical summary or other pertinent documents are obtained to promote continuity of care; if documents cannot be obtained, the reason must be noted in the integrated care record.

(d) The integrated care record format shall facilitate the ability to record the following information for each patient, as relevant:

(1) patient basic demographic information;

(2) patient physical health and behavioral health history:

(i) Physical health information

(a) physical examination reports

(b) diagnosis or medical impression

(c) diagnostic procedures/tests reports

(d) medical orders and anesthesia record

(e) immunization and drug history

(f) notation of allergic or adverse reactions to medications

(ii) Mental health information

(a) diagnosis or diagnostic impression

(b) psychosocial assessment

(c) mental health treatment history

(iii)Substance use information

(a) diagnosis or diagnostic impression

(b) the impact of the use of chemicals, including tobacco, on self and significant others

(c) prior periods of sustained recovery and how such recovery was Supported.

(3) admission note;

(4) assessment of the patient's goals regarding basic treatment goals and needs;

(5) treatment plan and applicable reviews;

(6) dated progress notes that relate to goals and objectives of treatment;

(7) discharge plan;

(8) documentation of the services provided and any referrals made;

(9) discharge summary;

(10) dated and signed records of all medications prescribed by the clinic and other prescription medications being used by the patient, if applicable;

(11) consent forms, if applicable; and

(12) record of contacts with collaterals if applicable.

(e) Patient case records must be retained for a minimum period of six (6) years from the date of the last service provided to a patient or, in the case of a minor, for at least six years after the last date of service or three years after he/she reaches majority whichever time period is longer.

(f) Confidentiality

(1) Notwithstanding any other New York State regulation, In cases where component providers of an integrated care services program are governed by different state or federal laws and regulations protecting clinical records and information, the integrated care record shall be governed by the state and federal privacy rules and regulations that give the most protection to the record, unless it is possible to redact provisions of the record with more protection without compromising the purpose for which the record is being disclosed.

(2) An integrated care services program providing chemical dependence services must obtain patient consent prior to making any disclosures from the integrated care

record, unless the disclosure is authorized as an exception pursuant to federal regulations.

(3) AIDS and HIV information shall only be disclosed in accordance with Article 27-F of the Public Health Law.

§ 404.14 Application and Approval

(a) Application and Approval Process.

(1) Providers that possess at least two licenses/certificates from at least two separate state licensing agencies and are seeking approval to integrate services for which they are licensed or certified may submit an application to the state licensing agency of the host site.

(2) Applications shall be submitted in a format prescribed for all applicants and reviewed by the state licensing agency that regulates the services to be added, in conjunction with the state licensing agency with authority for the host clinic, as appropriate.

(3) Applications shall include information needed to demonstrate that the provider is:

(a) licensed or certified by the relevant state licensing agencies to provide services for which the provider is seeking to integrate;

(b) in compliance with all applicable requirements of the relevant state licensing agencies.

(c) in good standing at the time of application approval. A provider is in good standing if each clinic site for which the provider is licensed or certified to offer services:

(i) is licensed by the Office of Mental Health and has a 1 year or greater time frame on operating certificate (Tier 3 providers are not eligible to participate); and/or

(ii) is certified by the Office of Alcoholism and Substance Abuse Services and all of its programs have an operating certificate with partial or substantial compliance (2 or 3 years); and/or

(iii) has an operating certificate from the Department of Health and not currently under any enforcement actions;

(d) in compliance with the physical plant requirements under this Part; and

(e) a member of a health home designated by the Commissioner of Health pursuant to section 365-l of the Social Services Law.

(4) Applications may include but not be limited to requests for information regarding services to be added and the plan for implementation, staffing, operating expenses and revenues, and utilization of services as they relate to integrated care services as described in this Part.

(5) The applicant shall supply any additional documentation or information requested by the state licensing agency of the host site, in conjunction with the other state licensing agencies as appropriate, within a stated timeframe of such request, unless an extension is obtained. The granting of a request for an extension shall be at the discretion of such state licensing agency of the host site. Failure to provide the additional documentation or information within the time prescribed shall constitute an abandonment or withdrawal of the application without any further action from the state licensing agency.

(6) The affected state licensing agency shall approve or disapprove an application in writing.

§ 404.15 Inspection

(a) The state licensing agency with authority for the host clinic shall have ongoing inspection responsibility for the integrated services clinic, pursuant to this Part. The purpose of the inspection is to ensure compliance with all applicable laws, rules, and regulations, as well as to determine the renewal term of the operating certificate or license, as applicable. The adjunct state licensing agency shall not duplicate inspection activities.

(b) The host state licensing agency shall consult with the adjunct state licensing agency on matters specific to the provision of such add-on services, as may be necessary to assure patient health and safety. Any significant deficiencies will immediately be referred for enforcement to the responsible state licensing agency. If at any point during the inspection, findings are identified that suggest imminent risk of serious harm or injury to patients, the inspector(s) will immediately contact their supervisor, who will consult with the adjunct state licensing agency, as applicable.

(c) Inspections shall be conducted utilizing a joint-licensing instrument, developed collaboratively by the three state licensing agencies. This standardized procedure will ensure consistency of the inspection process throughout the State and provide standardized reviews of the operations and services at each integrated services clinic. All deficiencies and/or corrective action will be overseen by the monitoring state licensing agency with notice to the adjunct state licensing agency or agencies, as applicable.

(d) Each integrated services clinic shall undergo an unannounced inspection which will occur prior to renewal of the Operating Certificate or License.

(1) At the start of the inspection, the inspector(s) will meet with integrated services clinic administrative staff to explain the purpose and scope of the inspection and request any documentation (e.g., policies; staffing information; etc.) that may be needed to facilitate the review.

(2) The inspection will include, but not be limited to, the following areas of review:

(f) on-site inspection of clinic appearance, conditions and general safety;

(g) evaluation of the sponsor, its management systems, and procedures;

(h) patient case record review;

(i) interviews of staff and patients;

(j) examination of staffing patterns and staff qualifications;

(k) analysis of statistical information contained in reports required to be submitted by the clinic;

(l) compliance with the reporting requirements;

(m) verification of staff credentials, as applicable;

(n) incident reporting requirements; and

(o) such other operating areas of activities as may be necessary or appropriate to determine compliance with applicable laws and regulations.

(3) At the conclusion of the inspection, the inspector(s) will meet with integrated services clinic administrative staff to discuss all deficiencies identified during the inspection.

(e) Upon completion of the inspection, a written report will be provided to the integrated services clinic which describes the results of the inspection, including each regulatory deficiency identified, if any. The provider of services shall take all actions necessary to correct all deficiencies reported. The provider of services shall submit a plan of correction to the state licensing agency with authority for the host clinic within 30 days, which states the specific actions taken or planned to achieve compliance with identified requirements. Any planned actions described in the plan of correction must be accompanied with a timetable for their implementation.

(f) If the provider of services fails, within the specified or an otherwise reasonable time, to correct any reported deficiencies, or fails to maintain satisfactory compliance with applicable laws, rules and regulations, the commissioner of the state licensing agency with authority for the host clinic may revoke, suspend or limit the operating certificate or license or levy a civil fine for such failures, in accordance with applicable regulations.

(g) Concurrently, each integrated services clinic shall undergo a fiscal viability review which will include an assessment of the financial information of the provider of services. Such information shall be submitted in intervals and in a form prescribed by the state licensing agency with authority for the host clinic, for compliance with minimum standards established by the state licensing agency, in order to determine the provider's fiscal capability to effectively support the authorized services.

(h) Providers of services that fail to meet the minimum standards of the state licensing agency with authority for the host clinic shall be required to submit a financial

recovery plan setting forth the specific actions to be taken to meet the minimum standards within a reasonable time frame.